



Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024

No. 50, 2024

**An Act to amend the *Therapeutic Goods Act 1989*
and other legislation in relation to vaping goods,
and for related purposes**

Note: An electronic version of this Act is available on the Federal Register of Legislation
(<https://www.legislation.gov.au/>)

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No. 50, 2024

**An Act to amend the *Therapeutic Goods Act 1989*
and other legislation in relation to vaping goods,
and for related purposes**

[Assented to 27 June 2024]

The Parliament of Australia enacts:

No. 50, 2024

*Therapeutic Goods and Other Legislation Amendment (Vaping
Reforms) Act 2024*

1

1 Short title

This Act is the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*.

2 Commencement

- (1) Each provision of this Act 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. Sections 1 to 4 and anything in this Act not elsewhere covered by this table | The day this Act receives the Royal Assent. | 27 June 2024 |
| 2. Schedule 1, Parts 1 to 3 | The later of: (a) 1 July 2024; and (b) the day after this Act receives the Royal Assent. | 1 July 2024 (paragraph (a) applies) |
| 2A. Schedule 1, items 50 to 57 | The later of: (a) 1 July 2024; and (b) the day after this Act receives the Royal Assent. | 1 July 2024 (paragraph (a) applies) |
| 2B. Schedule 1, items 57A and 57B | Immediately after the commencement of the provisions covered by table item 2. | 1 July 2024 |
| 2C. Schedule 1, Parts 5 to 11 | The later of: (a) 1 July 2024; and (b) the day after this Act receives the Royal Assent. | 1 July 2024 (paragraph (a) applies) |
| 3. Schedule 2 | The day after this Act receives the Royal Assent. | 28 June 2024 |

Commencement information

| Column 1 | Column 2 | Column 3 |
|---------------|---|----------------|
| Provisions | Commencement | Date/Details |
| 4. Schedule 3 | At the same time as the provisions covered by table item 2. | 1 July 2024 |
| 5. Schedule 4 | 1 October 2024. | 1 October 2024 |

Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

- (2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3 Schedules

Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Note 1: Subject to item 20 of Schedule 4, the provisions of the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* amended or inserted by this Act, and any other provisions of that instrument, may be amended or repealed by an instrument made under subsection 19(7A) of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).

Note 2: Subject to item 20 of Schedule 4, the provisions of the *Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024* amended or inserted by this Act, and any other provisions of that instrument, may be amended or repealed by an instrument made under subsection 52D(2) of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).

Note 3: Subject to item 20 of Schedule 4, the provisions of the *Therapeutic Goods (Medical Devices) Regulations 2002* and the *Therapeutic Goods Regulations 1990* amended or inserted by this Act, and any other provisions of those regulations, may be amended or repealed by regulations made under section 63 of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).

4 Review of operation of amendments

- (1) The Minister must cause an independent review to be conducted of the operation of the amendments made by Schedules 1, 3 and 4 to this Act and any regulations or other legislative instruments made for the purposes of those amendments.
- (2) The review must commence no later than 1 July 2027.
- (3) The persons who conduct the review must give the Minister a written report of the review within 6 months after the commencement of the review.
- (4) The Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of that House after the report is given to the Minister.

Schedule 1—Amendment of the Therapeutic Goods Act 1989

Part 1—Definitions and objects of Act

Therapeutic Goods Act 1989

1 Subsection 3(1) (after paragraph (b) of the definition of *therapeutic goods*)

Insert:

or (ba) determined to be therapeutic goods under subsection 7AAA(1);

2 Subsection 3(1) (paragraphs (e) and (f) of the definition of *therapeutic goods*)

After “section 7”, insert “and goods determined to be therapeutic goods under subsection 7AAA(1)”.

3 At the end of subsection 4(1)

Add:

- ; (d) provide for the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are:
- (i) imported into Australia; or
 - (ii) manufactured in Australia; or
 - (iii) supplied in Australia, whether manufactured in Australia or elsewhere; or
 - (iv) exported from Australia.

4 After section 7

Insert:

7AAA Minister may determine that goods are therapeutic goods

- (1) The Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods (other than goods declared not to be therapeutic goods under an order in force under section 7

and goods covered by a determination under subsection 7AA(1) or (2) (excluded goods)):

- (a) are therapeutic goods; or
 - (b) when used, advertised, or presented for supply in a particular way, are therapeutic goods.
- (2) Before making a determination under subsection (1), the Minister:
- (a) must have regard to the following matters:
 - (i) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;
 - (ii) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;
 - (iii) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme; and
 - (b) may have regard to any other relevant matter.

5 After paragraph 8(1)(b)

Insert:

- (ba) goods in relation to which the Minister is considering making a determination under subsection 7AAA(1) (goods that are therapeutic goods); or

Part 2—Regulation of vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

6 Subsection 3(1)

Insert:

commercial quantity of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

7 Subsection 3(1) (definition of *manufacture*)

After “therapeutic goods”, insert “, or vaping goods,”.

8 Subsection 3(1)

Insert:

medical practitioner means a person who is registered or licensed as a medical practitioner under a law of a State or an internal Territory that provides for the registration or licensing of medical practitioners.

nurse practitioner means a person who is registered, or authorised (however described) to practise, as a nurse practitioner by or under a law of a State or an internal Territory that provides for the registration of nurse practitioners, or the authorisation of persons to practise as nurse practitioners.

pharmacist means a person who is registered as a pharmacist under a law of a State or an internal Territory that provides for the registration of pharmacists.

9 Subsection 3(1) (paragraph (c) of the definition of *supply*)

After “goods”, insert “or vaping goods”.

10 Subsection 3(1)

Insert:

unit of vaping goods has the meaning prescribed by the regulations.

vaping accessory has the meaning given by section 41P.

vaping device has the meaning given by section 41P.

vaping goods has the meaning given by section 41P.

vaping substance has the meaning given by section 41P.

11 After Chapter 4

Insert:

Chapter 4A—Vaping goods

Part 4A-1—Introduction

Division 1—Introduction

41N Simplified outline of this Chapter

The importation into Australia of vaping goods, and the manufacture, supply or possession of vaping goods in Australia, is prohibited, subject to some exceptions. A person may commit an offence or be liable to a civil penalty for contravening the prohibitions (see Part 4A-2).

Definitions of *vaping goods* and related terms are set out in Division 2 of this Part. Vaping goods includes vaping substances, vaping accessories, vaping devices and goods determined by the Minister to be vaping goods.

The Minister may, by legislative instrument, determine that specified vaping goods, or a specified class of vaping goods, may be supplied or possessed in Australia:

- (a) by a specified person, or a specified class of persons; and
- (b) in the circumstances (if any) specified in the determination; and
- (c) subject to the conditions (if any) specified in the determination (see Part 4A-3).

The Secretary may, on application by a person, give the person consent to manufacture, supply or possess vaping goods. The consent may be given unconditionally or subject to conditions, and in respect of particular vaping goods or classes of vaping goods. In deciding whether to give a consent, the Secretary must comply with the decision-making principles (if any) determined by the Minister by legislative instrument. A person may commit an offence or be liable to a civil penalty if conditions of a consent are breached (see Part 4A-3).

41NA Relationship with other Chapters of this Act

An offence provision or civil penalty provision in this Chapter does not limit the generality of an offence provision or civil penalty provision in any other Chapter, and those provisions in other Chapters do not limit the generality of offence provisions or civil penalty provisions in this Chapter.

Division 2—Interpretation

41P Meaning of *vaping goods* and related terms

(1) In this Act:

vaping accessory means a cartridge, capsule, pod or other vessel:

- (a) that is for use in, or with, a vaping device; and
- (b) whether or not the cartridge, capsule, pod or other vessel:
 - (i) contains a vaping substance; or
 - (ii) is designed or intended to be refilled.

vaping device means:

- (a) a device (whether or not filled with a vaping substance) that generates or releases, or is designed or intended to generate

- or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user; or
- (b) a device to which paragraph (a) would apply if the device were not temporarily or permanently inoperable, incomplete, damaged or unfinished.

Note: Examples of devices that are not vaping devices include the following:

- (a) humidifiers;
- (b) diffusers;
- (c) nebulisers;
- (d) inhalers.

vaping goods means any of the following goods:

- (a) a vaping substance;
- (b) a vaping accessory;
- (c) a vaping device;
- (d) goods the presentation of which includes an express or implied representation that the goods are of a kind referred to in paragraph (a), (b) or (c);
- (e) goods that are, or are included in a class of goods that are, determined to be vaping goods under subsection (3).

Note: This definition is affected by subsection (2).

vaping substance:

- (a) means:
 - (i) nicotine in solution in any concentration (including in a salt or base form); or
 - (ii) any liquid or other substance for use in, or with, a vaping device; and
 - (b) includes a container (other than a vaping accessory or vaping device), or part of such a container, in which a liquid or other substance referred to in subparagraph (a)(i) or (ii) is present.
- (2) For the purposes of paragraph (d) of the definition of **vaping goods** in subsection (1):
- (a) the presentation of goods includes matters in relation to:
 - (i) the name of the goods; and
 - (ii) the labelling and packaging of the goods; and
 - (iii) any advertising or informational material associated with the use or supply of the goods; and

- (b) goods are taken to be presented as being a particular kind of goods even if the presentation:
 - (i) is capable of being misleading or confusing as to the content or proper use or identification of the goods; or
 - (ii) suggests that the goods have ingredients, components or characteristics that they do not have.

Minister may determine that goods are or are not vaping goods etc.

- (3) The Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods or specified classes of goods:
 - (a) are or are not vaping goods; or
 - (b) when used, advertised, or presented for use or supply in a particular way, are or are not vaping goods.

Part 4A-2—Offences and civil penalty provisions relating to vaping goods

Division 1—General

41Q Offences and civil penalty provision—importing vaping goods into Australia

Offences

- (1) A person commits an offence if the person imports vaping goods into Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence of strict liability if the person imports vaping goods into Australia.

Penalty: 200 penalty units.

Civil penalty provision

- (3) A person contravenes this subsection if the person imports vaping goods into Australia.

Maximum civil penalty:

- (a) for an individual—7,000 penalty units; and
(b) for a body corporate—70,000 penalty units.
- (4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods imported by the person into Australia.

Note: For *unit* of vaping goods, see subsection 3(1).

Exception

- (5) Subsections (1) to (4) do not apply if the importation of the vaping goods is not prohibited under the *Customs Act 1901*.

Note: The person bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

41QA Offences and civil penalty provision—manufacturing vaping goods in Australia

Offences

- (1) A person commits an offence if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence of strict liability if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Penalty: 200 penalty units.

Civil penalty provision

- (3) A person contravenes this subsection if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Maximum civil penalty:

- (a) for an individual—7,000 penalty units; and
 - (b) for a body corporate—70,000 penalty units.
- (4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of the manufacture, or the carrying out of the step in the manufacture, by the person of each unit of vaping goods.

Note: For *unit* of vaping goods, see subsection 3(1).

Exceptions

- (5) Subsections (1) to (4) do not apply if:
- (a) the vaping goods are therapeutic goods; and
 - (b) one of the following subparagraphs applies:
 - (i) the person is the holder of a licence in force under Part 3-3 that authorises the manufacture of the vaping goods, or the carrying out of the step in the manufacture of the vaping goods, at the manufacturing site where the manufacture, or the step, is carried out;
 - (ii) the person is the holder of a conformity assessment document that applies to the vaping goods;
 - (iii) the Secretary has given the person a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out the step in the manufacture of the vaping goods, and the manufacture, or the step, is carried out in accordance with the consent.

Note: The person bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

41QB Offences and civil penalty provision—supplying vaping goods

Offences

- (1) A person commits an offence if the person supplies vaping goods in Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence of strict liability if the person supplies vaping goods in Australia.

Penalty: 200 penalty units.

Civil penalty provision

- (3) A person contravenes this subsection if the person supplies vaping goods in Australia.

Maximum civil penalty:

- (a) for an individual—7,000 penalty units; and
- (b) for a body corporate—70,000 penalty units.

- (4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods supplied by the person in Australia.

Note: For *unit* of vaping goods, see subsection 3(1).

Exceptions—general

- (5) Subsections (1) to (4) do not apply if:
- (a) subsections (6), (7) and (8) apply in relation to the supply of the vaping goods by the person; or
 - (b) subsections (9), (10) and (11) apply in relation to the supply of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (6), (7) and (8) or subsections (9), (10) and (11): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Exceptions—wholesale supply chain

- (6) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the vaping goods are therapeutic goods that are entered on the Register; or
 - (b) both of the following apply:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;
 - (ii) the vaping goods are 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 conform with a standard applicable to the goods; or
 - (c) the vaping goods are covered by a determination made by the Minister under section 41R.
- (7) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the person:
 - (i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or
 - (ii) is otherwise approved under those regulations to import the vaping goods; or
 - (b) the person is the holder of a licence in force under Part 3-3 that authorises a step in the manufacture of the vaping goods; or
 - (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
 - (d) both of the following apply:
 - (i) the person is a wholesaler who is the holder of a licence, or is otherwise authorised, to supply one or more

- substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the supply occurs;
- (ii) the supply occurs in accordance with the licence or authority; or
- (e) both of the following apply:
- (i) the Secretary has given the person a consent under subsection 41RC(1) to supply the vaping goods;
 - (ii) the supply occurs in accordance with the consent; or
- (f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:
- (i) the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods; and
 - (ii) the supply occurs in accordance with the determination.
- (8) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the person (the *recipient*) to whom the vaping goods are supplied is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of vaping goods; or
 - (b) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; or
 - (c) the Secretary has given the recipient a consent under subsection 41RC(1) to supply the vaping goods; or
 - (d) in the case of vaping goods that are covered by a determination made by the Minister under section 41R—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods.

Exceptions—retail supply chain

- (9) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the vaping goods are therapeutic goods that are entered on the Register; or
 - (b) both of the following apply:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;
 - (ii) the vaping goods are 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 conform with a standard applicable to the goods; or
 - (c) the vaping goods are covered by a determination made by the Minister under section 41R.
- (10) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the person is a pharmacist; or
 - (b) the person is a medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the supply occurs.
- (11) This subsection applies in relation to the supply of the vaping goods by the person if:
- (a) the supply is:
 - (i) to another person for use by that person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; or

- (ii) to another person, who is the carer of a third person, for use by the third person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; and
- (b) if the vaping goods are, or contain, a vaping substance—the vaping substance is in final dosage form; and
- (c) the supply is:
 - (i) in accordance with this Act (apart from this section); and
 - (ii) consistent with the person’s authority to supply the vaping goods under a law of the State or Territory in which the supply occurs.

Meaning of final dosage form

- (12) For the purposes of paragraph (11)(b), a vaping substance is in **final dosage form** if the vaping substance is in a form that can be administered to a person without any change or modification (other than vaporisation).

41QC Offences and civil penalty provision—possessing at least commercial quantity of vaping goods

Offences—possessing at least commercial quantity but less than 100 times commercial quantity

- (1) A person commits an offence if:
 - (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 2 years or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) Absolute liability applies to paragraph (1)(b).
 - (3) A person commits an offence of strict liability if:
-

- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
- (b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: 120 penalty units.

Offences—possessing at least 100 times commercial quantity but less than 1,000 times commercial quantity

- (4) A person commits an offence if:
 - (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 4 years or 3,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (5) Absolute liability applies to paragraph (4)(b).
- (6) A person commits an offence of strict liability if:
 - (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: 240 penalty units.

Offences—possessing 1,000 times commercial quantity or more

- (7) A person commits an offence if:
 - (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (8) Absolute liability applies to paragraph (7)(b).
- (9) A person commits an offence of strict liability if:
- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: 420 penalty units.

Civil penalty provision

- (10) A person contravenes this subsection if:
- (a) the person possesses a quantity of a kind of vaping goods in Australia; and
 - (b) the quantity is at least the commercial quantity of that kind of vaping goods.

Maximum civil penalty:

- (a) for an individual—7,000 penalty units; and
 - (b) for a body corporate—70,000 penalty units.
- (11) A person who contravenes subsection (10) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia.

Note: For *unit* of vaping goods, see subsection 3(1).

Exception—possession for personal use

- (11A) Subsections (1) to (3) and (10) and (11) do not apply in relation to the possession of a quantity of a kind of vaping goods by the person if:
- (a) the vaping goods have been lawfully supplied to the person; and
 - (b) the vaping goods are for use by the person personally; and
 - (c) the quantity is less than 5 times the commercial quantity of that kind of vaping goods.
-

Note: The person bears an evidential burden in relation to the matters in subsection (11A): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Exceptions—general

- (12) Subsections (1) to (11) do not apply if subsections (13) and (14) apply in relation to the possession of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (13) and (14): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

- (13) This subsection applies in relation to the possession of the vaping goods by the person if:
- (a) the vaping goods are therapeutic goods that are entered on the Register; or
 - (b) both of the following apply:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;
 - (ii) the vaping goods are 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 conform with a standard applicable to the goods; or
 - (c) the vaping goods are covered by a determination made by the Minister under section 41R.
- (14) This subsection applies in relation to the possession of the vaping goods by the person if:
- (a) the person:
 - (i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or

- (ii) is otherwise approved under those regulations to import the vaping goods; or
- (b) the person is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) both of the following apply:
 - (i) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the person possesses the goods;
 - (ii) the possession of the goods is in accordance with the licence or authority; or
- (e) both of the following apply:
 - (i) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods;
 - (ii) the possession is in accordance with the consent; or
- (f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:
 - (i) the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods; and
 - (ii) the possession is in accordance with the determination.

41QD Offences and civil penalty provision—possessing less than commercial quantity of vaping goods

Offences

- (1) A person commits an offence if:
 - (a) the person is a retailer in relation to retail premises in Australia; and
 - (b) the person possesses a quantity of a kind of vaping goods at the retail premises; and

- (c) the quantity is less than the commercial quantity of that kind of vaping goods.

Penalty: Imprisonment for 12 months or 500 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) Absolute liability applies to paragraph (1)(b).
- (3) A person commits an offence of strict liability if:
- (a) the person is a retailer in relation to retail premises in Australia; and
 - (b) the person possesses a quantity of a kind of vaping goods at the retail premises; and
 - (c) the quantity is less than the commercial quantity of that kind of vaping goods.

Penalty: 60 penalty units.

Civil penalty provision

- (4) A person contravenes this subsection if:
- (a) the person is a retailer in relation to retail premises in Australia; and
 - (b) the person possesses a quantity of a kind of vaping goods at the retail premises; and
 - (c) the quantity is less than the commercial quantity of that kind of vaping goods.

Maximum civil penalty:

- (a) for an individual—1,000 penalty units; and
- (b) for a body corporate—10,000 penalty units.

- (5) A person who contravenes subsection (4) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person at the retail premises in Australia.

Note: For *unit* of vaping goods, see subsection 3(1).

Exceptions—general

- (6) Subsections (1) to (5) do not apply if subsections (7) and (8) apply in relation to the possession of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (7) and (8): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

- (7) This subsection applies in relation to the possession of the vaping goods by the person if:
- (a) the vaping goods are therapeutic goods that are entered on the Register; or
 - (b) both of the following apply:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;
 - (ii) the vaping goods are 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 conform with a standard applicable to the goods; or
 - (c) the vaping goods are covered by a determination made by the Minister under section 41R.
- (8) This subsection applies in relation to the possession of the vaping goods by the person if:
- (a) both of the following apply:
 - (i) the person is a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the person possesses the goods;
 - (ii) the possession of the goods is in accordance with the licence or authority; or

- (b) both of the following apply:
 - (i) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods;
 - (ii) the possession is in accordance with the consent; or
- (c) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:
 - (i) the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods; and
 - (ii) the possession is in accordance with the determination.

Exception—possession for personal use

- (9) Subsections (1) to (5) do not apply in relation to the possession of a quantity of a kind of vaping goods by the person if:
 - (a) the vaping goods are for use by the person personally; and
 - (b) the quantity is not more than the permitted quantity of that kind of vaping goods.

Note: The person bears an evidential burden in relation to the matters in subsection (9): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Definitions

- (10) In this section:

permitted quantity of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

retailer in relation to retail premises in Australia means any of the following:

- (a) an owner, lessee or occupier of retail premises in Australia;
- (b) a person conducting a business or undertaking at, or in connection or association with, retail premises in Australia;
- (c) a director, officer or agent of a person referred to in paragraph (a) or (b);
- (d) a person performing work in any capacity (including, but not limited to, an employee or a contractor) for, or on behalf of, a person referred to in paragraph (a), (b) or (c) at, or in connection or association with, retail premises in Australia.

retail premises means premises:

- (a) from which goods or services are available for supply, or are supplied, to a consumer; or
- (b) that are used in connection with the supply of goods or services to a consumer;

(whether or not the premises are used wholly or predominantly for that purpose).

Note: For *premises*, see subsection 3(1).

Division 2—Miscellaneous

41QE Exceptions etc. to civil penalty provisions—burden of proof

If, in proceedings for a pecuniary penalty order against a person for a contravention of a civil penalty provision in this Chapter, the person wishes to rely on any exception, exemption, excuse, qualification or justification that applies in relation to the civil penalty provision, then the person bears an evidential burden in relation to that matter.

Part 4A-3—Other provisions

Division 1—Determinations by Minister

41R Minister may determine that specified vaping goods may be supplied or possessed in Australia in specified circumstances etc.

The Minister may, by legislative instrument, determine that specified vaping goods, or a specified class of vaping goods, may be supplied or possessed in Australia:

- (a) by a specified person, or a specified class of persons; and
- (b) in the circumstances (if any) specified in the determination; and
- (c) subject to the conditions (if any) specified in the determination.

Note: Conditions may, for example, relate to the value or amount of specified vaping goods or the manner in which specified vaping goods may be supplied.

41RA Minister may determine other indications for which vaping goods may be used

The Minister may, by legislative instrument, determine, for the purposes of paragraph 41QB(11)(a), indications (other than smoking cessation or management of nicotine dependence) for which vaping goods may be used.

Division 2—Consent of Secretary

41RB Application to Secretary for consent to manufacture, supply or possess vaping goods

- (1) A person may apply to the Secretary for consent to manufacture, supply or possess vaping goods.
- (2) An application under subsection (1) must be in accordance with a form approved by the Secretary.

Further information

- (3) The Secretary may, by notice in writing given to the applicant, require the applicant to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice.

Applications or information may be given electronically

- (4) An approval of a form referred to in subsection (2), or a notice referred to in subsection (3), may require or permit an application or information to be given in accordance with specified software requirements:
 - (a) on a specified kind of data processing device; or
 - (b) by way of a specified kind of electronic transmission.

41RC Secretary may give consent

- (1) If:
-

- (a) a person (the **applicant**) has applied to the Secretary under section 41RB for consent to manufacture, supply or possess vaping goods; and
 - (b) the applicant has complied with any requirements made by the Secretary under subsection 41RB(3) in relation to the application;
- the Secretary must decide whether to give, or refuse to give, the consent.
- (2) The Secretary may give a consent under subsection (1):
 - (a) unconditionally or subject to conditions; or
 - (b) in respect of particular vaping goods or classes of vaping goods.
- Note: A person may commit an offence or be liable to a civil penalty if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given under subsection (1): see section 41RD.
- (2A) In making a decision under subsection (1), the Secretary must comply with the decision-making principles (if any) determined under subsection (2B).
 - (2B) The Minister may, by legislative instrument, determine principles (**decision-making principles**) that the Secretary must comply with in making a decision under subsection (1).
 - (2C) Without limiting subsection (2B), the decision-making principles may set out any of the following:
 - (a) circumstances in which a consent under subsection (1) must not be given;
 - (b) matters that must be taken into account in making a decision under subsection (1);
 - (c) matters that must not be taken into account in making a decision under subsection (1);
 - (d) matters that may be taken into account in making a decision under subsection (1).
 - (3) The Secretary must, as soon as practicable after making a decision to give a consent under subsection (1), cause particulars of the decision to be published on the Department's website.
-

- (4) If the Secretary decides to refuse to give a consent under subsection (1), the Secretary must, within 28 days after making the decision, notify the applicant in writing of the decision and the reasons for the decision.

41RD Offences and civil penalty provision—breaching condition of a consent

Offences

- (1) A person commits an offence if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2); and
 - (c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Penalty: 500 penalty units.

- (3) A person commits an offence of strict liability if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Penalty: 100 penalty units.

Civil penalty provision

- (4) A person contravenes this subsection if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Maximum civil penalty:

- (a) for an individual—3,000 penalty units; and
- (b) for a body corporate—30,000 penalty units.

Division 2—Other amendments

Therapeutic Goods Act 1989

12 Paragraph 14B(a)

After “(13AA)”, insert “or 41Q(1) or (2)”.

13 Paragraph 14B(a)

After “or (3)”, insert “or 41Q(3)”.

14 Subsection 19(9)

Repeal the subsection.

15 Subsection 30EK(6)

Repeal the subsection.

16 Subsection 30EL(1)

Omit “(1)” (first occurring).

17 Subsection 30EL(2)

Repeal the subsection.

18 Subsection 32CM(8)

Repeal the subsection.

19 At the end of section 41BG

Add:

Note: This section applies in relation to vaping goods that are a medical device.

20 Subsection 41HC(7)

Repeal the subsection.

21 Section 53A (after table item 33)

Insert:

33AA subsection 41RD(1) subsection 41RD(2)

22 Section 54BA (after table item 43)

Insert:

43AA Subsection 41Q(1)

43AB Subsection 41QA(1)

43AC Subsection 41QB(1)

43AD Subsection 41QC(1), (4) or (7)

43AE Subsection 41QD(1)

43AF Subsection 41RD(1)

23 After subsection 56A(4A)

Insert:

(4B) In proceedings for:

(a) an offence against a provision of section 41QA, 41QB, 41QC or 41QD; or

(b) the contravention of subsection 41QA(3), 41QB(3), 41QC(10) or 41QD(4) (civil penalty provisions);

a certificate by the Secretary to the effect that:

(c) the Secretary did not consent to the manufacture, supply or possession that is the subject of the proceedings; or

(d) the Secretary consented to that manufacture, supply or possession subject to conditions specified in the certificate;

is prima facie evidence of the matters specified in the certificate.

24 Subsection 57(10)

After “18A(1)”, insert “or 41P(3)”.

25 Subsection 60(1) (after paragraph (k) of the definition of *initial decision*)

Insert:

- (ka) refusing to give a consent under subsection 41RC(1), or giving such a consent subject to conditions imposed under subsection 41RC(2); or

Division 3—Application and transitional provisions

26 Application of amendments

The amendments of the *Therapeutic Goods Act 1989* made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 3—Advertising relating to vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

27 After Part 5-1

Insert:

Part 5-1A—Vaping goods

Division 1—Preliminary

42DZA This Part not to apply to certain advertisements for exported goods

This Part does not apply to advertisements that are solely for vaping goods that have been exported, or are intended exclusively for export, if the advertisements are not available to consumers in Australia.

42DZB Definitions

In this Part:

generic information, in relation to vaping goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of the vaping goods, but does not include:

- (a) an advertisement about the goods; or
- (b) generic information included in an advertisement about the goods; or
- (c) bona fide news.

Division 2—General provisions about advertising vaping goods

42DZC Authorised advertisements etc.

Secretary may authorise advertising

- (1) The Secretary may, by legislative instrument, authorise the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods.

Conditions

- (4) An authorisation under this section may be subject to conditions specified in the authorisation.
- (5) Without limiting subsection (4), conditions in an authorisation of advertising may relate to any of the following:
- (a) the nature of the audience to which the advertising is targeted;
 - (b) the form of the advertising;
 - (c) the content of the advertising;
 - (d) representations or information on:
 - (i) the labels of specified vaping goods or a specified class of vaping goods; or
 - (ii) the packages in which specified vaping goods or a specified class of vaping goods are contained; or
 - (iii) any material included with the package in which specified vaping goods or a specified class of vaping goods are contained.

Division 3—Offences and civil penalty provisions

42DZD Offences—no authorisation or conditions of authorisation not complied with

- (1) A person commits an offence if:
- (a) the person:
 - (i) advertises, by any means, vaping goods; or

- (ii) causes the advertising, by any means, of vaping goods;
and
- (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence of strict liability if:
 - (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods;
and
 - (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Penalty: 200 penalty units.

Continuing offences

- (3) A person who contravenes subsection (1) or (2) commits a separate offence in respect of each day (including a day of a conviction for

the offence or any later day) during which the contravention continues.

- (4) The maximum penalty for each day that an offence against subsection (1) or (2) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DZE Civil penalty—no authorisation or conditions of authorisation not complied with

- (1) A person contravenes this subsection if:
- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
 - (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Maximum civil penalty:

- (a) for an individual—7,000 penalty units; and
- (b) for a body corporate—70,000 penalty units.

Continuing contraventions

- (2) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).
- (3) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Division 4—Secretary may require information or documents

42DZF Secretary may require information or documents

Advertisements

- (1) The Secretary may, by written notice given to a person apparently responsible for advertising vaping goods, or for causing the advertising of vaping goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

- (2) The Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information in relation to vaping goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

- (3) The person must give the information, or produce the documents, to the Secretary:
 - (a) within the period, of not less than 14 days after the day the notice is given, specified in the notice or within such longer period as the Secretary allows; and
 - (b) in the form specified in the notice.

Note: A person may commit an offence under section 42DZG for failing to comply with the notice or giving false or misleading information or documents and may be liable to a civil penalty under section 42DZH for giving false or misleading information or documents.

- (4) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:
 - (a) on a specified kind of data processing device; or
 - (b) by way of a specified kind of electronic transmission.

Notice not a legislative instrument

- (5) A notice under subsection (1) or (2) is not a legislative instrument.

42DZG Offences—failing to comply with a notice etc.

- (1) A person commits an offence if:
- (a) the person is given a notice under subsection 42DZF(1) or (2); and
 - (b) the person fails to comply with the notice.

Penalty: 500 penalty units.

- (2) A person commits an offence of strict liability if:
- (a) the person is given a notice under subsection 42DZF(1) or (2); and
 - (b) the person fails to comply with the notice.

Penalty: 100 penalty units.

- (3) A person commits an offence if:
- (a) the person is given a notice under subsection 42DZF(1) or (2); and
 - (b) the person gives information or produces a document in compliance or purported compliance with the notice; and
 - (c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

- (4) A person commits an offence of strict liability if:
- (a) the person is given a notice under subsection 42DZF(1) or (2); and
 - (b) the person gives information or produces a document in compliance or purported compliance with the notice; and
 - (c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

42DZH Civil penalty—giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

- (a) the person is given a notice under subsection 42DZF(1) or (2); and
- (b) the person gives information or produces a document in compliance or purported compliance with the notice; and
- (c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

42DZJ Self-incrimination

- (1) A person is not excused from giving information or producing a document under section 42DZF on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.
- (2) However, in the case of an individual:
 - (a) the information given or the document produced; and
 - (b) giving the information or producing the document; and
 - (c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;are not admissible in evidence against the individual:
 - (d) in criminal proceedings, except proceedings for an offence against subsection 42DZG(3) or (4); or
 - (e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DZH.

Division 5—Directions about advertisements or generic information

42DZK Directions about advertisements or generic information

Advertisements

- (1) If, in relation to the advertising of vaping goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the vaping goods, or for causing the advertising of the vaping goods, to do one or more of the following:
 - (a) cease the advertisement;
 - (b) make a retraction;
 - (c) make a correction;
 - (d) recover any advertisement that is still in circulation;
 - (e) destroy the advertisement;
 - (f) cease making a particular claim or representation made by the advertisement.

Generic information

- (2) If, in relation to the dissemination of generic information in relation to vaping goods to the public or a section of the public, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following:
 - (a) withdraw the generic information;
 - (b) make a retraction;
 - (c) make a correction;
 - (d) recover any generic information that is still in circulation;
 - (e) destroy the generic information;
 - (f) cease making a particular claim or representation made by the generic information.

Conditions

- (3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.
- (4) Without limiting subsection (3), the conditions may relate to one or more of the following:
 - (a) the period for doing a thing the subject of the direction;
 - (b) in relation to the making of a retraction or correction—either or both of the following:
 - (i) the form and manner of the retraction or correction;
 - (ii) the period for which the retraction or correction must be made publicly available;
 - (c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

- (5) A direction under subsection (1) or (2) is not a legislative instrument.

Publication

- (6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

42DZL Offences—contravening direction under section 42DZK

- (1) A person commits an offence if:
 - (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2) in relation to vaping goods; and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction; and
 - (d) either:
 - (i) the use of the vaping goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

- (ii) the use of the vaping goods, if the vaping goods were used, would result in, or would be likely to result in, harm or injury to any person; and
- (e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

- (2) A person commits an offence if:
 - (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

- (3) A person commits an offence of strict liability if:
 - (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
 - (b) the person does an act or omits to do an act; and
 - (c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

42DZM Civil penalty—contravening direction under section 42DZK

A person contravenes this section if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and

- (c) the act or omission contravenes the direction or a condition of the direction.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

Division 6—Public warning notices

42DZN Secretary may issue a public warning notice

- (1) The Secretary may issue to the public a written notice containing a warning about vaping goods if:
 - (a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:
 - (i) the advertising of the vaping goods; or
 - (ii) the dissemination of generic information in relation to the vaping goods to the public or a section of the public; and
 - (b) the Secretary is satisfied that it is in the public interest to issue the notice.
- (2) If:
 - (a) the Secretary has given a person a notice (the **substantiation notice**) under subsection 42DZF(1) or (2); and
 - (b) the person fails to comply with the substantiation notice; and
 - (c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.
- (3) Subsection (2) does not limit subsection (1).
- (4) A notice under this section is not a legislative instrument.

Division 2—Other amendments

Therapeutic Goods Act 1989

28 Subsection 3(1) (definition of *advertise*)

After “therapeutic goods”, insert “or vaping goods”.

29 Section 5A

Omit “and sections 22A, 32DO, 41FE”, substitute “, sections 22A, 32DO and 41FE, subsections 42DZD(1) and (2) and sections 42DZG, 42DZL”.

30 Subparagraph 25(1)(fa)(ii)

After “5-1”, insert “or 5-1A”.

31 Paragraphs 30(1)(f) and (fa)

After “42DV(1)”, insert “or 42DZK(1)”.

32 Paragraph 30(1)(fb)

After “5-1”, insert “or 5-1A”.

33 Paragraphs 30(2)(eaa) and (eab)

After “42DV(1)”, insert “or 42DZK(1)”.

34 Subparagraph 30(2)(ea)(ii)

After “5-1”, insert “or 5-1A”.

35 Subparagraph 31(1)(h)(ii)

After “5-1”, insert “or 5-1A”.

36 Subparagraph 31(2)(gaa)(ii)

After “5-1”, insert “or 5-1A”.

37 Subparagraph 41FD(h)(ii)

After “5-1”, insert “or 5-1A”.

38 Paragraphs 41GL(g) and (ga)

After “42DV(1)”, insert “or 42DZK(1)”.

39 Paragraph 41GL(h)

After “5-1”, insert “or 5-1A”.

40 Paragraphs 41GN(1)(i) and (j)

After “42DV(1)”, insert “or 42DZK(1)”.

41 Subparagraph 41GN(1)(k)(ii)

After “5-1”, insert “or 5-1A”.

42 Subparagraph 41JA(1)(h)(ii)

After “5-1”, insert “or 5-1A”.

43 After section 42AC

Insert:

42AD This Part not to apply to advertisements about vaping goods

- (1) This Part does not apply in relation to advertisements about vaping goods.
- (2) Part 5-1A applies in relation to advertisements about vaping goods.

44 After subsection 42DLB(10)

Insert:

Continuing contraventions

- (10A) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).
- (10B) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

45 After subsection 42DMA(2)

Insert:

Continuing contraventions

- (2A) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).
- (2B) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

46 Section 53A (after table item 33D)

Insert:

33E subsection 42DZL(1) subsection 42DZL(2)

47 Section 54BA (after table item 43D)

Insert:

43E Subsection 42DZD(1)

43F Subsection 42DZL(1)

48 Subsection 60(1) (at the end of the definition of *initial decision*)

Add:

; or (m) under subsection 42DZK(1) or (2).

Division 3—Application and transitional provisions

49 Application of amendments

The amendments of the *Therapeutic Goods Act 1989* made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 4—Enforceable directions and forfeiture

Therapeutic Goods Act 1989

50 Subsection 3(1) (paragraph (b) of the definition of authorised person)

After “Part 6-2”, insert “or 6-2A”.

51 At the end of Chapter 5A

Add:

Part 5A-5—Enforceable directions

42YS Simplified outline of this Part

If the Secretary believes, on reasonable grounds, that:

- (a) a person is not complying with this Act or an instrument made under this Act in relation to particular goods; and
- (b) it is necessary to exercise powers under this Part to protect the health and safety of humans;

the Secretary may, by written notice, give directions to the person requiring the person to do specified things in relation to the goods within the period specified in the notice and at the person’s own cost.

The person may commit an offence or be liable to a civil penalty if the person fails to comply with the notice.

42YT Secretary may give directions if this Act or an instrument is not being complied with

- (1) This section applies if the Secretary believes, on reasonable grounds, that:
 - (a) a person is not complying with this Act or an instrument made under this Act in relation to particular goods; and

- (b) it is necessary to exercise powers under this section to protect the health and safety of humans.

Note: Paragraph (b) covers protecting the health and safety of humans in relation to the environment.

- (2) The Secretary may, by written notice, give directions to the person requiring the person to do any of the following, within the period specified in the notice and at the person's own cost:
- (a) relabel, or label, the goods in compliance with this Act or the instrument;
 - (b) repackage the goods in compliance with this Act or the instrument;
 - (c) destroy or otherwise dispose of the goods;
 - (d) deliver the goods to a specified person to be destroyed or otherwise disposed of in an appropriate manner;
 - (e) any other thing prescribed by the regulations in relation to the goods.

Note: For variation and revocation of the directions, see subsection 33(3) of the *Acts Interpretation Act 1901*.

- (3) A period specified in a notice given under subsection (2) must be reasonable having regard to the circumstances.

Offence

- (4) A person commits an offence if:
- (a) the person is given a notice under subsection (2); and
 - (b) the person fails to comply with the notice within the period specified in the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Civil penalty provision

- (5) A person contravenes this subsection if:
- (a) the person is given a notice under subsection (2); and
 - (b) the person fails to comply with the notice within the period specified in the notice.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

52 At the end of section 48H

Add:

Note: This section does not apply in relation to the thing if section 52AAB applies in relation to the thing: see subsection 52AAB(2).

53 At the end of section 48J

Add:

Note: This section does not apply in relation to the thing if section 52AAB applies in relation to the thing: see subsection 52AAB(2).

54 After Part 6-2

Insert:

Part 6-2A—Forfeiture of things seized

52AAA Forfeiture of things seized under search warrant in certain circumstances

- (1) If:
 - (a) an authorised person seizes a thing under a warrant issued under section 50; and
 - (b) the Secretary believes, on reasonable grounds, that:
 - (i) the thing has been imported, manufactured or supplied in contravention of this Act or an instrument made under this Act; or
 - (ii) the thing has been in the possession, custody or control of a person in contravention of this Act or an instrument made under this Act; or
 - (iii) a requirement under this Act, or an instrument made under this Act, has not been complied with in relation to the thing;
- the thing is forfeited to the Commonwealth.

Notice of forfeiture

- (2) The Secretary must give a written notice (a *forfeiture notice*) in accordance with subsection (3) to:
- (a) the owner of the thing; or
 - (b) if the owner cannot be identified after reasonable inquiry—the person who had possession, custody or control of the thing immediately before it was seized.
- (3) The forfeiture notice must identify the thing and state the following:
- (a) the day the thing was seized;
 - (b) that the thing was seized under a warrant issued under section 50 of this Act and the grounds on which it was seized;
 - (c) that the thing is forfeited to the Commonwealth;
 - (d) that the owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, may, within 2 months beginning on the day the forfeiture notice is given, commence proceedings against the Commonwealth in a court of competent jurisdiction for a declaration that the thing is not forfeited to the Commonwealth.

Proceedings may be commenced for declaration that thing is not forfeited to the Commonwealth

- (4) The owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, may, subject to subsection (5), commence proceedings in a court of competent jurisdiction for a declaration that the thing is not forfeited to the Commonwealth.
- (5) Proceedings:
- (a) may be commenced under subsection (4) even if the forfeiture notice required to be given under subsection (2) in relation to the thing has not yet been given; and
 - (b) may only be commenced before the end of the period of 2 months beginning on the day the forfeiture notice is given.

Secretary may retain or dispose of forfeited thing

(6) If:

- (a) the owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, does not, within the period of 2 months beginning on the day the forfeiture notice was given, commence proceedings against the Commonwealth for a declaration that the thing is not forfeited to the Commonwealth; or
- (b) the owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, commences such proceedings within that 2 month period, but at the end of the proceedings (including an appeal to a court in relation to the proceedings), the court has not made a declaration that the thing is not forfeited to the Commonwealth;

then:

- (c) the thing is condemned as forfeited to the Commonwealth; and
- (d) the Secretary may cause notice of the forfeiture of the thing to be published on the Department's website; and
- (e) the Secretary may:
 - (i) retain the thing for the purpose of proceedings in respect of which the thing may afford evidence; or
 - (ii) cause the thing to be disposed of in such manner as the Secretary directs.

Note: See also section 54 (offences and forfeiture).

52AAB Return or retention of thing declared not to be forfeited to the Commonwealth

- (1) This section applies in relation to a thing if:
 - (a) the thing was forfeited to the Commonwealth under subsection 52AAA(1); and
 - (b) a court has made a declaration that the thing is not forfeited to the Commonwealth under that subsection.
- (2) Sections 48H and 48J do not apply in relation to the thing.

- (3) At the end of 120 days after the declaration referred to in paragraph (1)(b) was made, an authorised person must take reasonable steps to return the thing to the person from whom it was seized unless:
- (a) proceedings in respect of which the thing may afford evidence were commenced before the end of the 120 days and have not been completed (including an appeal to a court in relation to those proceedings); or
 - (b) an authorised person may retain the thing because of an order under subsection (6); or
 - (c) an authorised person is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State or Territory) to retain, destroy or dispose of the thing.
- (4) The thing may be returned under subsection (3) either unconditionally or on such terms and conditions as the Secretary sees fit.
- (5) The Secretary may apply to an issuing officer for an order that an authorised person may retain the thing for a further period. The application must be made:
- (a) before the end of 120 days after the declaration referred to in paragraph (1)(b) was made; or
 - (b) if an order has been made under subsection (6)—before the end of the period specified in the most recent order made under that subsection.
- (6) If the issuing officer is satisfied that it is necessary for an authorised person to continue to retain the thing:
- (a) for the purposes of an investigation as to whether an offence against this Act has been committed; or
 - (b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution; or
 - (c) for the purposes of an investigation as to whether a civil penalty provision has been contravened; or
 - (d) to enable evidence of a contravention of a civil penalty provision to be secured for the purposes of civil proceedings;
- the issuing officer may order that an authorised person may retain the thing for a period (not exceeding 3 years) specified in the order.
-

- (7) Before making an application under subsection (5), the Secretary must:
- (a) take reasonable steps to discover who has an interest in the retention of the thing; and
 - (b) if it is practicable to do so, notify each person who the Secretary believes to have such an interest of the proposed application.

55 Application of amendment

Part 6-2A of the *Therapeutic Goods Act 1989*, as inserted by item 54 of this Schedule, applies in relation to the following:

- (a) a thing (including vaping goods) that is seized by an authorised person, under a warrant issued under section 50 of that Act, on or after the commencement of this item;
- (b) vaping goods that were seized by an authorised person, under a warrant issued under section 50 of that Act, before the commencement of this item, if the vaping goods are in the custody of the authorised person immediately before that commencement.

56 Subsection 54(3)

After “therapeutic goods”, insert “or vaping goods”.

57 At the end of section 54

Add:

Note: See also Part 6-2A, which provides for forfeiture of things seized under a warrant in certain circumstances.

57A Subsection 60(1) (at the end of the definition of *initial decision*)

Add:

; or (n) to give directions under subsection 42YT(2).

57B After subsection 60(2D)

Insert:

- (2E) If the Secretary or a delegate of the Secretary makes a decision to give directions under subsection 42YT(2), a person is not entitled

Schedule 1 Amendment of the Therapeutic Goods Act 1989

Part 4 Enforceable directions and forfeiture

to request the Minister to reconsider the decision unless the person is the person to whom the directions were given.

Part 5—Entry, searches and warrants

Therapeutic Goods Act 1989

58 Subsection 3(1)

Insert:

issuing officer means:

- (a) a magistrate; or
- (b) a registrar or other officer of a court of a State or Territory who is authorised under a law of the State or Territory to issue search warrants.

59 Paragraphs 46A(1)(b) and (2)(b)

After “therapeutic goods” (wherever occurring), insert “or vaping goods”.

60 Before subparagraph 46A(4)(a)(ia)

Insert:

- (iaa) who is required to comply with a condition of an exemption of vaping goods under section 18 or 41HA; or

61 Paragraph 48(1)(b)

After “therapeutic goods” (wherever occurring), insert “or vaping goods”.

62 Subsection 48A(3)

Omit “magistrate”, substitute “issuing officer”.

63 Subparagraph 48AA(2)(b)(ii)

Omit “a magistrate”, substitute “an issuing officer”.

64 Subsection 48AA(3)

Omit “a magistrate”, substitute “an issuing officer”.

65 Subsection 48AA(5)

Omit “A magistrate”, substitute “An issuing officer”.

66 Paragraph 48AA(5)(b)

Omit “magistrate”, substitute “issuing officer”.

67 Subsections 48BA(7) and 48C(7)

Omit “a magistrate”, substitute “an issuing officer”.

68 Section 48J (heading)

Omit “Magistrate”, substitute “Issuing officer”.

69 Subsection 48J(1)

Omit “a magistrate” (wherever occurring), substitute “an issuing officer”.

70 Subsection 48J(2)

Omit “magistrate” (wherever occurring), substitute “issuing officer”.

71 Subsection 49(1)

Omit “a magistrate”, substitute “an issuing officer”.

72 Subsections 49(2) and (3)

Omit “magistrate” (wherever occurring), substitute “issuing officer”.

73 Subsection 50(1)

Omit “a magistrate”, substitute “an issuing officer”.

74 Subsections 50(2) and (3)

Omit “magistrate” (wherever occurring), substitute “issuing officer”.

75 Subsection 51(1)

Omit “a magistrate”, substitute “an issuing officer”.

76 Subsections 51(4) to (9)

Omit “magistrate” (wherever occurring), substitute “issuing officer”.

77 Subsection 51(10)

Omit “a magistrate”, substitute “an issuing officer”.

78 Paragraph 51B(2)(a)

Omit “a magistrate”, substitute “an issuing officer”.

79 Paragraph 51B(2)(a)

Omit “that magistrate”, substitute “that issuing officer”.

80 Paragraph 51B(2)(b)

Omit “magistrate”, substitute “issuing officer”.

81 Subparagraphs 51B(2)(c)(i) and (ii)

Omit “a magistrate”, substitute “an issuing officer”.

82 Paragraph 51B(2)(d)

Omit “a magistrate”, substitute “an issuing officer”.

83 After section 51B

Insert:

51C Issuing officers—personal capacity

Powers conferred personally

- (1) A power conferred on an issuing officer by this Part is conferred on the issuing officer:
 - (a) in a personal capacity; and
 - (b) not as a court, or as a member or an officer of a court.

Powers need not be accepted

- (2) The issuing officer need not accept the power conferred.

Protection and immunity

- (3) An issuing officer exercising a power conferred by this Part has the same protection and immunity as if the issuing officer were exercising the power:

Schedule 1 Amendment of the Therapeutic Goods Act 1989

Part 5 Entry, searches and warrants

- (a) as the court of which the issuing officer is a member or an officer; or
- (b) as a member or an officer of the court of which the issuing officer is a member or an officer.

Part 6—Delegation and authorised persons

Therapeutic Goods Act 1989

84 Section 7A

Before “The Secretary”, insert “(1)”.

85 At the end of section 7A

Add:

- (2) In exercising a power under a provision of this Act under an authorisation under subsection (1), the authorised person must comply with any directions of the Secretary.

86 After subsection 57(1)

Insert:

- (1A) The Secretary may, by signed instrument, delegate all or any of the Secretary’s powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant) or section 52AAB (return or retention of thing declared not to be forfeited) to an officer of:
- (a) a Department of State of a State; or
 - (b) a Department or administrative unit of the Public Service of a Territory; or
 - (c) an authority of a State or of a Territory;
being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement. This subsection does not limit subsection (1).

87 At the end of section 57

Add:

Delegate must comply with directions

- (12) In performing any functions or exercising any powers under a delegation under this section, the delegate must comply with any directions of the person who delegated the function or power.

88 Subsection 61A(4) (at the end of paragraph (c) of the definition of *protected person*)

Add “or (1A)”.

Part 7—Release of information

Therapeutic Goods Act 1989

89 Subsection 61(1)

Insert:

vaping goods information means information in relation to vaping goods that is held by the Department and relates to the performance of the Department’s functions.

90 After subsection 61(7)

Insert:

- (7A) The Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection (7B) vaping goods information of a kind specified under that subsection for a purpose specified under that subsection.
- (7B) For the purposes of subsection (7A), the Minister may, by legislative instrument, specify one or more of the following:
- (a) a person, body or authority;
 - (b) kinds of persons, bodies or authorities;
 - (c) kinds of vaping goods information;
 - (d) purposes.
- (7C) The Secretary may release to the public vaping goods information of a kind specified under subsection (7D).
- (7D) The Minister may, by legislative instrument, specify kinds of vaping goods information for the purpose of subsection (7C).

91 Subsection 61(8)

Omit “therapeutic goods information provided to the Department in relation to a matter”, substitute “therapeutic goods information, or vaping goods information, held by the Department in relation to a matter”.

92 Paragraphs 61(8)(a) and (b)

After “therapeutic goods”, insert “or vaping goods”.

93 Subsection 61(8) (note)

Omit “provided to”, substitute “held by”.

94 Subsection 61(9)

Omit “or (5D)”, substitute “, (5D), (7B) or (7D)”.

95 Application of amendments

The amendments made by this Part apply in relation to the release, disclosure or use of information on or after the commencement of this Part, whether the information started to be held, or was obtained or created, before or after that commencement.

Part 8—Laboratory testing

Therapeutic Goods Act 1989

96 Paragraph 63(2)(d)

Repeal the paragraph, substitute:

- (d) provide for the procedures to be followed in the sampling and testing of any of the following:
 - (i) therapeutic goods;
 - (ii) vaping goods;
 - (iii) any kind of goods, for the purpose of ascertaining whether or not they are therapeutic goods or vaping goods; and

97 Saving of regulations

Regulations made for the purposes of paragraph 63(2)(d) of the *Therapeutic Goods Act 1989* that are in force immediately before the commencement of this item continue in force for the purposes of that paragraph as in force on or after that commencement.

98 Paragraph 63(2)(g)

After “therapeutic goods” (wherever occurring), insert “or vaping goods”.

Part 9—Approvals for certain Part 3-2 exempt goods

Therapeutic Goods Act 1989

99 Subsection 19(1)

Omit “registered goods, listed goods or exempt goods”, substitute “registered goods or listed goods”.

Part 10—Offences and civil penalty provisions for breach of condition of certain exemptions or approvals

Therapeutic Goods Act 1989

100 After subsection 22(5A)

Insert:

- (6) A person commits an offence if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission results in the breach of:
 - (i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1);
or
 - (ii) a condition of an approval or authority under section 19;
or
 - (iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or
 - (iv) a condition of an approval under section 19A; and
 - (c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

101A Subparagraph 22(7)(b)(ii)

After “approval”, insert “or authority”.

101 At the end of subsection 22(7)

Add:

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

102 Subsection 22(7AA)

Repeal the subsection, substitute:

(7AA) A person commits an offence of strict liability if:

- (a) the person does an act or omits to do an act; and
- (b) the act or omission results in the breach of:
 - (i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1);
or
 - (ii) a condition of an approval or authority under section 19;
or
 - (iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or
 - (iv) a condition of an approval under section 19A.

Penalty: 100 penalty units.

103 Section 22AA (heading)

Omit “a condition of an exemption”, substitute “conditions”.

104 Section 22AA

Before “A person”, insert “(1)”.

105 Section 22AA

Omit “this section”, substitute “this subsection”.

106 At the end of section 22AA

Add:

- (2) A person contravenes this subsection if:
 - (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches:
 - (i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1);
or
 - (ii) a condition of an approval or authority under section 19;
or

- (iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or
- (iv) a condition of an approval under section 19A.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

107 Subsection 41HA(2) (note)

Omit “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

108 Subsection 41HB(2) (note)

Omit “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

109 Subsection 41HB(7) (note)

Omit “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

110 Subsection 41HD(7) (note)

Omit “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

111 Subsection 41MN(9)

Repeal the subsection, substitute:

Offences relating to breaching a condition of an exemption, approval or authority, or a condition applicable under regulations

- (9) A person commits an offence if:
 - (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches:
 - (i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or
 - (ii) a condition of an approval under section 41HB; or
 - (iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or

Schedule 1 Amendment of the Therapeutic Goods Act 1989

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- (iiia) a condition of an authority under section 41HC; or
- (iv) a condition of an approval under subsection 41HD(1), (1A) or (2); and
- (c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (9A) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(9A) A person commits an offence if:

- (a) the person does an act or omits to do an act; and
- (b) the act or omission breaches:
 - (i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or
 - (ii) a condition of an approval under section 41HB; or
 - (iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or
 - (iiia) a condition of an authority under section 41HC; or
 - (iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(9B) A person commits an offence of strict liability if:

- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches:
 - (i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or
 - (ii) a condition of an approval under section 41HB; or
 - (iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or
 - (iiia) a condition of an authority under section 41HC; or
 - (iv) a condition of an approval under subsection 41HD(1), (1A) or (2).
-

Penalty: 100 penalty units.

112 After subsection 41MNA(2)

Insert:

- (2A) A person contravenes this subsection if:
- (a) the person does an act or omits to do an act; and
 - (b) the act or omission breaches:
 - (i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or
 - (ii) a condition of an approval under section 41HB; or
 - (iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or
 - (iiia) a condition of an authority under section 41HC; or
 - (iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

113 Section 53A (after table item 9A)

Insert:

9B subsection 22(6) subsection 22(7)

114 Section 53A (after table item 31)

Insert:

31AA subsection 41MN(9) subsection 41MN(9A)

115 Section 54BA (table item 5)

After “22(2)”, insert “, (6)”.

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116 Section 54BA (table item 40)

After “(5)”, insert “, (9)”.

117 Application of amendments

The amendments of the *Therapeutic Goods Act 1989* made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 11—Other amendments

Therapeutic Goods Act 1989

118 After subsection 58(2)

Insert:

(2A) The Secretary may issue export certification for vaping goods for use in humans that are not goods for which export certification may be issued under subsection (1).

Note: Export certification for vaping goods that are for therapeutic use in humans may be issued under subsection (1).

(2B) A State or Territory must not issue export certifications for vaping goods for which export certification may be issued under subsection (2A).

119 Subsection 61A(4) (after paragraph (g) of the definition of *protected person*)

Insert:

(ga) a person of a kind prescribed by the regulations;

120 Subsection 61A(4) (paragraph (h) of the definition of *protected person*)

Omit “(f) or (g)”, substitute “(f), (g) or (ga)”.

121 Subsection 62(1)

Omit “An APS employee in the Department”, substitute “A protected person”.

122 Subsection 62(2)

Omit “an APS employee in the Department”, substitute “a protected person”.

123 At the end of section 62

Add:

(3) In this section:

protected person means any of the following:

- (a) an APS employee in the Department;
- (b) a person of a kind prescribed by the regulations.

Schedule 2—Amendment of the Customs Act 1901

Customs Act 1901

1 Subsection 183UA(1)

Insert:

vaping goods has the same meaning as in regulation 5A of the
Customs (Prohibited Imports) Regulations 1956.

2 After subsection 206(2A)

Insert:

Vaping goods

(2B) If:

- (a) goods are seized under a seizure warrant or under subsection 203B(2) or (2A), 203CA(3) or 203CB(2); and
- (b) the Comptroller-General of Customs is satisfied that the goods are vaping goods that are prohibited imports;

the Comptroller-General of Customs may cause the goods to be dealt with in such manner as the Comptroller-General considers appropriate (including the destruction of the goods).

3 Subsection 206(3)

Omit “(2) or (2A)”, substitute “(2), (2A) or (2B)”.

4 Paragraph 206(5)(c)

Omit “(2) or (2A)”, substitute “(2), (2A) or (2B)”.

5 Subsections 206(6) and (7)

Omit “(2) or (2A)”, substitute “(2), (2A) or (2B)”.

Schedule 3—Amendments of other Acts

Industrial Chemicals Act 2019

1 Section 8

After “therapeutic purposes”, insert “, in vaping goods”.

2 Section 9 (after paragraph (d) of the definition of *industrial use*)

Insert:

(da) use as a vaping good (within the meaning of the *Therapeutic Goods Act 1989*) or in the preparation of such a good;

Public Health (Tobacco and Other Products) Act 2023

3 Section 64

After “5-1”, insert “or 5-1A”.

4 Section 64

After “therapeutic good”, insert “, or a vaping good,”.

Schedule 4—Supply of therapeutic vaping goods by pharmacists without prescription

Part 1—Amendments

Therapeutic Goods Act 1989

1 Subparagraph 41QB(7)(d)(i)

Omit “Schedule 4”, substitute “Schedule 3”.

2 Paragraphs 41QB(8)(b) and (10)(b)

Omit “Schedule 4”, substitute “Schedule 3”.

3 Subparagraph 41QC(14)(d)(i)

Omit “Schedule 4”, substitute “Schedule 3”.

4 Subparagraph 41QD(8)(a)(i)

Omit “Schedule 4”, substitute “Schedule 3”.

Therapeutic Goods (Medical Devices) Regulations 2002

5 Schedule 4 (table item 2.17, column headed “Conditions”)

Omit “Schedule 4 to the current Poisons Standard” (wherever occurring), substitute “Schedule 3 to the current Poisons Standard”.

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

6 Paragraph 5A(2)(c)

After “medical practice”, insert “or good nursing practice (as the case requires)”.

7 Paragraphs 5A(2)(d) and (e)

After “medical practitioner”, insert “or nurse practitioner”.

8 Subsection 5A(3) (heading)

Repeal the heading, substitute:

Supply by a pharmacist—with prescription

9 Subsection 5A(3)

Omit “health practitioner”, substitute “pharmacist”.

10 Subsection 5A(4)

Omit “health practitioner” (wherever occurring), substitute “pharmacist”.

11 At the end of section 5A

Add:

Supply by a pharmacist—without prescription

- (5) A pharmacist is authorised to supply a therapeutic good to a patient where:
- (a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and
 - (b) the therapeutic good is in the dosage form specified in column 3 of that item; and
 - (c) the therapeutic good is to be administered by the route specified in column 4 of that item; and
 - (d) the supply is for the indication specified in column 5 of that item; and
 - (e) the supply is to a patient who is 18 years of age or over; and
 - (f) the pharmacist requests and sights evidence of the patient’s identity and age; and
 - (g) the quantity of the goods does not exceed the quantity that is reasonably required for a patient’s therapeutic use for 1 month and that quantity is supplied to the patient only once in a month; and
 - (h) the concentration of nicotine in the goods does not exceed 20 mg/mL; and

- (i) the conditions specified in subsections (6) and (7) are satisfied.
- (6) The pharmacist must:
- (a) inform the patient, or a parent or a guardian of the patient, that the therapeutic good is not a listed good or registered good; and
 - (b) obtain informed consent from the patient, or a parent or a guardian of the patient, in relation to, and before, the supply of the therapeutic good; and
 - (c) supply the therapeutic good in accordance with good pharmacy practice; and
 - (d) provide professional advice to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight and severity of condition, length of treatment, suitable titration, and interactions with other medicines; and
 - (e) provide contact details about smoking cessation support services to the patient; and
 - (f) if the pharmacist becomes aware that the patient has suffered an adverse event in relation to the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
 - (g) if the pharmacist becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.
- (7) The pharmacist must store the therapeutic good in a part of the pharmacy premises to which the public does not have access.

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12 Subsection 49(1) (table item 27, column 1)

Before “4”, insert “3 or”.

13 In the appropriate position in Schedule 3

Insert:

NICOTINE in therapeutic vaping goods (within the meaning of the *Therapeutic Goods Regulations 1990*) in final dosage form for smoking cessation or the management of nicotine dependence when:

- (a) for supply to persons aged 18 years and over; and
- (b) the pharmacist requests and sights evidence of the patient's identity and age; and
- (c) the pharmacist provides professional advice to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight and severity of condition, length of treatment, suitable titration, and interactions with other medicines; and
- (d) the pharmacist provides contact details about smoking cessation support services to the patient; and
- (e) the quantity of the goods does not exceed the quantity that is reasonably required for a patient's therapeutic use for 1 month and that quantity is supplied to the patient only once in a month; and
- (f) the concentration of nicotine in the goods does not exceed 20 mg/mL; and

except:

- (g) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (h) in tobacco prepared and packed for smoking.

14 Schedule 4 (entry for "NICOTINE")

Repeal the entry, substitute:

NICOTINE in preparations for human use **except:**

- (a) when included in Schedule 3; or
- (b) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (c) in tobacco prepared and packed for smoking.

15 Schedule 7 (paragraph (a) of the entry for “NICOTINE”)

Before “4”, insert “3 or”.

16 Index (entry for “NICOTINE”)

After:

Schedule 4

insert:

Schedule 3

Therapeutic Goods Regulations 1990

17 Schedule 5A (table item 15, column 3)

Omit “Schedule 4 to the current Poisons Standard” (wherever occurring), substitute “Schedule 3 to the current Poisons Standard”.

Part 2—Application and other provisions

18 Application of amendments

The amendments made by this Schedule apply in relation to the import, manufacture, possession or supply of therapeutic goods on or after the day this Schedule commences.

19 Amendments of current Poisons Standard

Provisions of the *Therapeutic Goods Act 1989*, or the *Therapeutic Goods Regulations 1990*, in relation to the requirements or procedure for amending the current Poisons Standard (within the meaning of that Act) do not apply to the amendments of the current Poisons Standard made by this Schedule.

20 Restrictions on amending instruments

- (1) A legislative instrument made under the *Therapeutic Goods Act 1989* (other than paragraph 52D(2)(b)) that:
 - (a) is made on or after the commencement of this Schedule; and
 - (b) amends or repeals the amendments made by this Schedule (other than the amendments of the current Poisons Standard);must not commence before the end of the period in which the instrument could be disallowed in either House of the Parliament.
- (2) Subitems (3) and (4) apply in relation to a legislative instrument made under paragraph 52D(2)(b) of the *Therapeutic Goods Act 1989* that:
 - (a) is made on or after the commencement of this Schedule; and
 - (b) amends or repeals the amendments of the current Poisons Standard made by this Schedule.
- (3) Despite subsection 52D(4A) of the *Therapeutic Goods Act 1989*, section 42 (disallowance) of the *Legislation Act 2003* applies to the legislative instrument, to the extent that it amends or repeals the amendments of the current Poisons Standard made by this Schedule.
- (4) The legislative instrument must not commence before the end of the period in which it could be disallowed in either House of the Parliament.

- (5) A person must not make an application under subsection 52EAA(1) of the *Therapeutic Goods Act 1989* for:
- (a) an amendment of the entry relating to nicotine inserted into Schedule 3 to the current Poisons Standard by this Schedule;
or
 - (b) an amendment of the entry relating to nicotine inserted into Schedule 4 to the current Poisons Standard by this Schedule;
or
 - (c) any amendment related to the entries relating to nicotine referred to in paragraphs (a) and (b) of this subitem.
- (6) This item is repealed at the end of the day the report of the review required by section 4 of this Act is tabled in both Houses of the Parliament.
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[*Minister's second reading speech made in—
House of Representatives on 21 March 2024
Senate on 16 May 2024*]

(32/24)
