



Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 14 December 2023

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

Contents

1	Name.....	1
2	Commencement	1
3	Authority.....	1
4	Schedules.....	1
Schedule 1—Amendment of the Therapeutic Goods Regulations 1990		2
Part 1—Main amendments		2
<i>Therapeutic Goods Regulations 1990</i>		2
Part 2—Transitional provisions		8
<i>Therapeutic Goods Regulations 1990</i>		8
Schedule 2—Amendment of the Therapeutic Goods (Medical Devices) Regulations 2002		10
Part 1—Main amendments		10
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		10
Part 2—Transitional provisions		15
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		15

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 January 2024.	1 January 2024

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendment of the Therapeutic Goods Regulations 1990

Part 1—Main amendments

Therapeutic Goods Regulations 1990

1 Regulation 2

Insert:

disposable therapeutic vape means a therapeutic good:

- (a) that is a vaping device of the kind referred to in paragraph (a) of the definition of ***vaping device*** in this regulation; and
- (b) that is fully assembled with all the constituent components fixed permanently in place and that is not designed or intended (by the person under whose name the vaping device is or is to be supplied) to be disassembled; and
- (c) that is pre-filled with a therapeutic vaping substance; and
- (d) that is not designed or intended (by the person under whose name the vaping device is or is to be supplied) to be refilled.

2 Regulation 2 (definition of ***nicotine vaping product***)

Repeal the definition.

3 Regulation 2

Insert:

therapeutic vaping device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

therapeutic vaping device accessory has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

therapeutic vaping good means:

- (a) a therapeutic vaping device; or
- (b) a therapeutic vaping device accessory; or
- (c) a therapeutic vaping substance; or
- (d) a therapeutic vaping substance accessory.

therapeutic vaping kit means a kit, covered by subsection 7B(1) of the Act, that:

- (a) contains one or more therapeutic vaping substances or therapeutic vaping substance accessories; and
- (b) does not contain any other goods.

therapeutic vaping pack means a primary pack that:

- (a) contains 2 or more therapeutic vaping goods, including at least one therapeutic vaping device or therapeutic vaping device accessory; and
- (b) does not contain any other goods.

therapeutic vaping substance means a therapeutic good that is a liquid or other substance designed or intended for use in or with a vaping device.

therapeutic vaping substance accessory means a therapeutic good that is a cartridge, capsule, pod or other vessel:

- (a) that contains a therapeutic vaping substance (whether or not the vessel is designed or intended to be refilled); and
- (b) that is designed or intended for use in or with a therapeutic vaping device.

vaping device means:

- (a) a device 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 were the device not incomplete, damaged, temporarily or permanently inoperable, or unfinished.

Note 1: Examples of devices that are not vaping devices include the following:

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

Note 2: To avoid doubt, therapeutic vaping substance accessories and therapeutic vaping device accessories are not devices to which paragraph (b) applies.

4 Subregulations 12(5) to (7)

Repeal the subregulations.

5 Subregulation 12B(1B) (table item 58, column 5)

After “smoking cessation”, insert “or management of nicotine dependence”.

6 At the end of subregulation 48(1AB)

Add:

- ; (c) a decision to make goods the subject of a determination as referred to in paragraph (e) of column 3 of item 15 of the table in Schedule 5A.

7 After Part 1 of Schedule 3

Insert:

Part 2—Therapeutic goods that are not medicines

Item No.	Therapeutic goods
1	Therapeutic vaping substances, or therapeutic vaping substance accessories, to which item 1 in Part 1 of this Schedule does not apply

8 Schedule 4 (at the end of the table)

Add:

- 17 a therapeutic vaping kit, if each of the goods in the kit is a registered good

9 Schedule 5 (table item 1, column 2, after paragraph (a))

Insert:

- (b) the goods are not any of the following:
 - (i) disposable therapeutic vapes;

- (ii) therapeutic vaping substances;
- (iii) therapeutic vaping substance accessories;
- (iv) a therapeutic vaping kit;
- (v) goods in a therapeutic vaping pack; and

10 Schedule 5 (after table item 1)

Insert:

- 1A therapeutic goods that are disposable therapeutic vapes, therapeutic vaping substances or therapeutic vaping substance accessories, imported into Australia by a person (the *first person*) on board a ship or aircraft, if:
- (a) the therapeutic goods are for use in the treatment of the first person or one or more other persons on board the ship or aircraft under the care of the first person; and
 - (b) the importation of the therapeutic goods meets the requirements of paragraph 5(2)(b) or subregulation 5A(2) of the *Customs (Prohibited Imports) Regulations 1956*

11 Schedule 5 (table items 5 and 5A)

Repeal the items.

12 Schedule 5 (at the end of the cell at table item 9, column 2)

Add:

- ; or (c) the starting materials are nicotine in solution imported for use as an ingredient in a therapeutic good; or
- (d) the starting materials are ingredients or components imported for use in the manufacture of:
- (i) a therapeutic vaping substance; or
 - (ii) a therapeutic vaping substance accessory

13 Schedule 5A (cell at table item 1, column 2)

Repeal the cell, substitute:

Therapeutic goods imported into Australia, if:

- (a) the goods are not any of the following:
 - (i) disposable therapeutic vapes;
 - (ii) therapeutic vaping substances;
 - (iii) therapeutic vaping substance accessories;
 - (iv) a therapeutic vaping kit;
 - (v) goods in a therapeutic vaping pack; and
- (b) the goods are held under the direct control of the sponsor, until the goods are:
 - (i) the subject of a notification under item 3; or
 - (ii) approved for importation into

- Australia under subsection 19(1), section 19A, subsection 32CK(1) or section 32CO of the Act; or
- (iii) authorised for supply under subsection 19(5) or 32CM(1) of the Act; or
- (iv) authorised for supply under rules made under subsection 19(7A) or 32CM(7A) of the Act; or
- (v) dispensed as a medicine or biological prescribed for a Category A patient within the meaning of subregulation 12A(5); or
- (vi) exported from Australia

14 Schedule 5A (at the end of the table)

Add:

- 15 Therapeutic goods, if:
- (a) the goods are:
 - (i) therapeutic vaping substances; or
 - (ii) therapeutic vaping substance accessories; or
 - (iii) a therapeutic vaping kit; or
 - (iv) goods in a therapeutic vaping pack; and
 - (b) the goods are not, or do not include, any medicinal cannabis products; and
 - (c) the only indications of the goods are use for smoking cessation or the management of nicotine dependence; and
 - (d) the sponsor of the goods, and any other person involved in the wholesale or retail supply of the
 - (a) the sponsor must give the Secretary a notice (the *sponsor notice*), in a form approved in writing by the Secretary, stating that:
 - (i) the goods conform with any standard applicable to the goods, or are imported or supplied (as the case may be) with the consent of the Secretary under section 14 or 14A of the Act; and
 - (ii) the only indications of the goods are use for smoking cessation or the management of nicotine dependence; and
 - (b) the sponsor notice must be given:
 - (i) for goods imported into Australia—before importing the goods; or
 - (ii) for goods manufactured in Australia—before the goods are released for supply in Australia; and
 - (c) the sponsor holds information or evidence to support the statements made in the sponsor notice; and
 - (d) neither of the statements made in the sponsor notice is incorrect; and
 - (e) the goods are not the subject of a determination, by the Secretary and published on the Department’s website, that the supply of the goods be stopped or

goods, intend the goods to be supplied to the ultimate consumer of the goods in accordance with an approval or authority under section 19 of the Act

should cease because:

- (i) the Secretary is satisfied that the supply compromises public health and safety; or
 - (ii) the Secretary is satisfied that the goods do not conform with a standard applicable to the goods; and
- (f) the sponsor must:
- (i) if requested by the Secretary, give the Secretary the information or evidence referred to in paragraph (c); and
 - (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made); and
- (g) for goods manufactured in Australia—the goods are manufactured by:
- (i) the holder of a licence; or
 - (ii) a person who is exempt in accordance with subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the goods; and
- (h) the goods may be supplied to a person who is not the ultimate consumer of the goods only if:
- (i) the supply is to the holder of a licence; or
 - (ii) the supply is to a person who is exempt in accordance with subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the goods; or
 - (iii) the supply is to a person (a **registered pharmacist**) who is registered as a pharmacist under a law of a State or Territory providing for the registration of pharmacists; or
 - (iv) the supply is to any other person who is authorised, under the law of the State or Territory in which that person deals with goods, to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and the supply is in accordance with that authorisation; and
- (i) the goods may be supplied to the ultimate consumer of the goods only if:
- (i) the goods are supplied as a finished product; and
 - (ii) the supply is by a registered pharmacist or by another person who is authorised, under the law of a State or Territory, to supply one or more substances included in Schedule 4 to the current Poisons Standard to an ultimate consumer; and
 - (iii) the supply is in accordance with an approval or authority under section 19 of the Act; and
 - (iv) if the supply is by a person authorised as described in subparagraph (ii), the supply is in accordance with that authorisation; and
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- (j) the sponsor must:
 - (i) keep records relating to the source and supply of the goods; and
 - (ii) if requested by the Secretary, give the records to the Secretary within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made); and
- (k) the sponsor must provide information of a kind mentioned in subsection 29A(2) or 29AA(2) of the Act relating to the goods to the Secretary within the following periods:
 - (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the sponsor becomes aware of the event or occurrence;
 - (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the goods, or another person—10 days after the sponsor becomes aware of the event or occurrence;
 - (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the goods, or another person—30 days after the sponsor becomes aware of the event or occurrence;
 - (iv) in any other case—60 days after the sponsor becomes aware of the information

16	Therapeutic goods imported into Australia, if: <ul style="list-style-type: none">(a) the goods are nicotine in solution as a starting material for use in the manufacture of a therapeutic vaping substance, a therapeutic vaping substance accessory or any other therapeutic good; or(b) the goods are any other starting materials that are ingredients or components for use in the manufacture of a therapeutic vaping substance or a therapeutic vaping substance accessory	(a) the sponsor must give the Secretary a notice (the <i>sponsor notice</i>), in a form approved in writing by the Secretary, stating that the goods are for use in the manufacture, in accordance with the requirements of the Act, of another therapeutic good by a manufacturer that holds all relevant licences or approvals (however described) required under the following: <ul style="list-style-type: none">(i) Part 3-3 of the Act;(ii) the law of the State or Territory in which the manufacture is to occur; and (b) the sponsor notice must be given before importing the goods; and (c) the goods may be supplied only for use in manufacture as referred to in paragraph (a)
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Part 2—Transitional provisions

Therapeutic Goods Regulations 1990

15 Division 14 of Part 9

Repeal the Division.

16 Regulation 80

Repeal the regulation.

17 In the appropriate position in Part 9

Insert:

Division 23—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023

93 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*.

94 Approving supply of therapeutic goods under authorised prescriber scheme

The amendment of subregulation 12B(1B) of these Regulations made by Schedule 1 to the amending regulations applies in relation to an authority given under subsection 19(5) of the Act on or after 1 January 2024.

95 Goods to be included in parts of the Register

The amendments of Schedules 3 and 4 to these Regulations made by Schedule 1 to the amending regulations apply to therapeutic vaping substances, therapeutic vaping substance accessories and therapeutic vaping kits from 1 January 2024.

96 Exempt goods

- (1) Paragraph (b) of item 1 of the table in Schedule 5 to these Regulations, and item 1A of the table in Schedule 5 to these Regulations, as inserted by Schedule 1 to the amending regulations, apply in relation to:
 - (a) disposable therapeutic vapes imported on or after 1 January 2024; and
 - (b) any other therapeutic goods imported on or after 1 March 2024.
- (2) The repeal of items 5 and 5A of the table in Schedule 5 to these Regulations, and of the definition of *nicotine vaping product* in regulation 2 of these Regulations, by Schedule 1 to the amending regulations applies in relation to:
 - (a) disposable therapeutic vapes imported or manufactured on or after 1 January 2024; and
 - (b) any other therapeutic goods imported or manufactured on or after 1 March 2024.

- (3) The amendment of item 9 of the table in Schedule 5 to these Regulations made by Schedule 1 to the amending regulations applies in relation to starting materials imported on or after 1 March 2024.
- (4) The amendment of item 1 of the table in Schedule 5A to these Regulations made by Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after 1 March 2024.
- (5) Item 15 of the table in Schedule 5A to these Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to therapeutic goods imported or manufactured on or after 1 March 2024.
- (6) Item 16 of the table in Schedule 5A to these Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to therapeutic goods imported on or after 1 March 2024.

97 Transitional vaping manufacturers—exemption from Part 3-3 of the Act

- (1) For the purposes of this regulation, a person is a *transitional vaping manufacturer* if:
 - (a) the person carries out, on or after 1 January 2024, a step in the manufacture of therapeutic goods that are:
 - (i) a therapeutic vaping substance; or
 - (ii) a therapeutic vaping substance accessory; or
 - (iii) a therapeutic vaping kit; or
 - (iv) goods in a therapeutic vaping pack; and
 - (b) the person was, as at 2 May 2023, carrying out an equivalent step in the manufacture of other goods that were the same kind of goods as the therapeutic goods referred to in paragraph (a) except that the other goods were not therapeutic goods; and
 - (c) before carrying out the step referred to in paragraph (a), the person has notified the Secretary, in a form approved under subregulation (2), in relation to the step referred to in paragraph (b).
- (2) The Secretary may, in writing, approve a form for the purposes of paragraph (1)(c).

Exemption

- (3) For the purposes of subsection 34(2) of the Act, the transitional vaping manufacturer is exempt from the operation of Part 3-3 of the Act in relation to the step in manufacture referred to in paragraph (1)(a) of this regulation.

When exemption ceases

- (4) Subregulation (3) ceases to have effect on 1 December 2024.

Schedule 2—Amendment of the Therapeutic Goods (Medical Devices) Regulations 2002

Part 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulations 7.1(4) to (7)

Repeal the subregulations (not including the heading).

2 At the end of subregulation 10.7(1A)

Add:

- ; (c) a decision to make a medical device the subject of a determination as referred to in paragraph (e) of the column headed “Conditions” in item 2.17 of the table in Part 2 of Schedule 4.

3 Part 1 of Schedule 4 (table item 1.1, column headed “Kinds of medical devices”, after paragraph (a))

Insert:

(ab) the device is not a device referred to in item 1.1A; and

4 Part 1 of Schedule 4 (after table item 1.1)

Insert:

1.1A Medical devices that are therapeutic vaping devices, therapeutic vaping device accessories, therapeutic cannabis vaping devices or therapeutic cannabis vaping device accessories, imported into Australia by a person (the *first person*) on board a ship or aircraft, if:

- (a) the medical devices are for use in the treatment of the first person or one or more other persons on board the ship or aircraft who are under the care of the first person; and
- (b) the importation of the medical devices meets the requirements of paragraph 5(2)(b) or subregulation 5A(2) of the *Customs (Prohibited Imports) Regulations 1956*

5 Part 1 of Schedule 4 (table items 1.5 and 1.6)

Repeal the items.

6 Part 2 of Schedule 4 (cell at table item 2.1, column headed “Kinds of medical devices”)

Repeal the cell, substitute:

Medical device that is imported into Australia, if:

- (a) the device is not a device referred to in item 2.17; and
- (b) the device is held under the direct control of the sponsor, until the device is:
 - (i) the subject of a notification under item 2.3; or
 - (ii) approved for importation into Australia under section 41HB or 41HD of the Act; or

- (iii) authorised for supply under section 41HC of the Act; or
- (iv) used for a Category A patient, within the meaning of regulation 7.2; or
- (v) exported from Australia

7 Part 2 of Schedule 4 (table item 2.1, column headed “Conditions”, after paragraph (b))

Insert:

- (c) For a device that is a therapeutic cannabis vaping good—the sponsor has, before importing the device, given the Secretary a notice, in a form approved in writing by the Secretary, stating that:
 - (i) the device complies with the essential principles, or is imported or supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act; and
 - (ii) the sponsor holds information or evidence to support the statement made for the purposes of subparagraph (i).

8 Part 2 of Schedule 4 (table item 2.11A)

Repeal the item.

9 Part 2 of Schedule 4 (at the end of the table)

Add:

- 2.17 Medical device that is:
 - (a) a therapeutic vaping device; or
 - (b) a therapeutic vaping device accessory
 - (a) The sponsor must give the Secretary a notice (the *sponsor notice*), in a form approved in writing by the Secretary, stating that:
 - (i) the device is intended, by the person under whose name the device is or is to be supplied, only to administer or contain a therapeutic vaping substance whose only indications are use for smoking cessation or the management of nicotine dependence; and
 - (ii) the device complies with the essential principles, or is imported or supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act.
 - (b) The sponsor notice must be given:
 - (i) for a device imported into Australia—before importing the device; or
 - (ii) for a device manufactured in Australia—before the device is first supplied in Australia.
 - (c) The sponsor holds information or evidence to support the statements made in the sponsor notice.
 - (d) Neither of the statements made in the sponsor notice is incorrect.
 - (e) The device is not the subject of a determination, by the Secretary and published on the Department’s website, that the supply of the device be stopped or should cease because:
 - (i) the Secretary is satisfied that the supply
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- compromises public health and safety; or
 - (ii) the Secretary is satisfied that the device does not comply with the essential principles.
 - (f) The sponsor must:
 - (i) if requested by the Secretary, give the Secretary the information or evidence referred to in paragraph (c); and
 - (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made).
 - (g) The device may be supplied to a person who is not the ultimate consumer of the device only if:
 - (i) the supply is to the holder of a licence; or
 - (ii) the supply is to a person who is exempt in accordance with subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the device; or
 - (iii) the supply is to a person (a **registered pharmacist**) who is registered as a pharmacist under a law of a State or Territory providing for the registration of pharmacists; or
 - (iv) the supply is to any other person who is authorised, under the law of the State or Territory in which that person deals with goods, to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and the supply is in accordance with that authorisation.
 - (h) The device may be supplied to the ultimate consumer of the device only if:
 - (i) the device is supplied as a finished product; and
 - (ii) the supply is by a registered pharmacist or by another person who is authorised, under the law of a State or Territory, to supply one or more substances included in Schedule 4 to the current Poisons Standard to an ultimate consumer; and
 - (iii) if the supply is by a person authorised as described in subparagraph (ii), the supply is in accordance with that authorisation.
 - (i) The sponsor must:
 - (i) keep records relating to the source and supply of the device; and
 - (ii) if requested by the Secretary, give the records to the Secretary within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made).
 - (j) The sponsor must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2)

of the Act relating to the device to the Secretary within the following periods:

- (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the sponsor becomes aware of the event or occurrence;
- (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the sponsor becomes aware of the event or occurrence;
- (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the sponsor becomes aware of the event or occurrence;
- (iv) in any other case—60 days after the sponsor becomes aware of the information.

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- 2.18 Medical device imported into Australia, if the medical device is a component or article imported for use in the manufacture of:
- (a) a therapeutic vaping device; or
 - (b) a therapeutic vaping device accessory
- (a) The sponsor must give the Secretary a notice (the ***sponsor notice***), in a form approved in writing by the Secretary, stating that the device is for use in the manufacture, in accordance with the requirements of the Act, of a therapeutic vaping device or a therapeutic vaping device accessory by a manufacturer that holds all relevant licences or approvals (however described) required under the law of the State or Territory in which the manufacture is to occur.
- (b) The sponsor notice must be given before importing the device.
- (c) The device may be supplied only for use in manufacture as referred to in paragraph (a).

10 Dictionary

Insert:

therapeutic cannabis vaping device means a medical device that:

- (a) is a vaping device (within the meaning of the *Therapeutic Goods Regulations 1990*) other than a disposable therapeutic vape (within the meaning of that instrument); and
- (b) is intended, by the person under whose name the device is or is to be supplied, to be used only to administer medicinal cannabis products or medicines containing synthetic cannabis.

therapeutic cannabis vaping device accessory means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel that is designed or intended:

- (a) to contain a therapeutic vaping substance; and
- (b) only for use in or with a therapeutic cannabis vaping device; and
- (c) to be refillable.

therapeutic cannabis vaping good means a therapeutic cannabis vaping device or a therapeutic cannabis vaping device accessory.

therapeutic vaping device means a therapeutic good that is a vaping device (within the meaning of the *Therapeutic Goods Regulations 1990*) other than:

- (a) a disposable therapeutic vape (within the meaning of that instrument); or
- (b) a therapeutic cannabis vaping device.

therapeutic vaping device accessory means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel that is designed or intended:

- (a) to contain a therapeutic vaping substance; and
- (b) for use in or with a therapeutic vaping device; and
- (c) to be refillable;

but does not include a therapeutic cannabis vaping device accessory.

therapeutic vaping substance has the same meaning as in the *Therapeutic Goods Regulations 1990*.

Part 2—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

11 Subregulation 11.51(1)

Repeal the subregulation.

12 Subregulations 11.58(1) to (5)

Repeal the subregulations.

13 Regulation 11.65

Repeal the regulation.

14 In the appropriate position in Part 11

Insert:

Division 11.19—Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023

11.73 Application of amendments

The amendments of these Regulations made by Part 1 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (other than the amendments of the Dictionary) apply in relation to therapeutic goods imported or manufactured on or after 1 March 2024.