



Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

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

Dated 28 June 2024

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.....	2
Schedule 1—Main amendments		3
Part 1—Amendments		3
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		3
<i>Therapeutic Goods Regulations 1990</i>		6
Part 2—Transitional provisions		11
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		11
<i>Therapeutic Goods Regulations 1990</i>		12
Schedule 2—Commercial quantities		14
<i>Therapeutic Goods Regulations 1990</i>		14
Schedule 3—Other amendments		15
<i>Therapeutic Goods Regulations 1990</i>		15

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

2 Commencement

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

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	At the same time as Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	1 July 2024
2. Schedule 1	At the same time as Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	1 July 2024
3. Schedule 2	The day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	1 October 2024
4. Schedule 3	The later of: (a) immediately after the commencement of Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> ; and (b) immediately after the commencement of Part 2 of the <i>Therapeutic Goods Law Application Act 2024</i> (WA). However, the provisions do not commence at all if the event mentioned in paragraph (b) does not occur.	30 August 2024 (paragraph (b) applies)

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—Main amendments

Part 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Paragraph 10.6(2)(a)

Omit “registered in a State or internal Territory and”.

2 Part 1 of Schedule 4 (table item 1.1, column headed “Kinds of medical devices”, paragraph (d))

Omit “registered under a law of a State or Territory”.

3 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraph (b))

Repeal the paragraph, substitute:

- (b) The sponsor notice must be given as follows:
- (i) for a device imported into Australia on or after 1 March 2024—before the device is imported;
 - (ii) for a device imported into Australia before 1 March 2024—before the earlier of the time the device is supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences;
 - (iii) for a device manufactured in Australia on or after 1 March 2024—before the device is first supplied in Australia;
 - (iv) for a device manufactured in Australia before 1 March 2024—before the earlier of the time the device is supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences.

4 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraph (g))

Repeal the paragraph, substitute:

- (fa) The sponsor must:
- (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the device; 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).
- (fb) The sponsor must allow an authorised officer:
- (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the device; and
 - (ii) while on those premises, to inspect those premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on those premises that relates to the device; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises.
- (fc) The sponsor must, if requested to do so by an authorised officer, produce to the authorised officer such documents relating to the device as the authorised officer requires and allow the authorised officer to copy the documents.
- (fd) If the sponsor is not the manufacturer of the device, the sponsor must have procedures in place to ensure that the manufacturer of the device allows an authorised officer:

- (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the device; and
 - (ii) while on those premises, to inspect those premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on those premises that relates to the device; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises.
- (fe) If the sponsor is not the manufacturer of the device, the sponsor must have procedures in place to ensure that the manufacturer of the device, if the manufacturer is requested to do so by an authorised officer, produces to the authorised officer such documents relating to the device as the authorised officer requires and allow the authorised officer to copy the documents.
- (g) The device may be supplied to a person who is not the ultimate consumer of the device only if:
- (i) the person (the **recipient**) to whom the device is supplied is the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of vaping goods; or
 - (ii) 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
 - (iii) the Secretary has given the recipient a consent under subsection 41RC(1) of the Act to supply the device; or
 - (iv) in the case of a device that is covered by a determination made by the Minister under section 41R of the Act—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to the device.

5 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, subparagraph (h)(ii))

Repeal the subparagraph, substitute:

- (ii) the supply is by 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 recipient carries on a business, practises or is employed; and

6 Part 2 of Schedule 4 (table item 2.18, column headed “Kinds of medical devices”, paragraphs (a) and (b))

Repeal the paragraphs, substitute:

- (a) a therapeutic vaping device; or
- (b) a therapeutic vaping device accessory; or
- (c) a therapeutic cannabis vaping good

7 Part 2 of Schedule 4 (table item 2.18, column headed “Conditions”, paragraph (a))

Omit “or a therapeutic vaping device accessory”, substitute “, a therapeutic vaping device accessory or a therapeutic cannabis vaping good”.

8 Part 2 of Schedule 4 (table item 2.18, column headed “Conditions”, after paragraph (b))

Insert:

- (ba) The sponsor must:
 - (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the device; 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).

9 Dictionary (paragraph (a) of the definition of *health professional*)

Before “a dentist”, insert “or”.

10 Dictionary (definition of *medical practitioner*)

Repeal the definition.

11 Dictionary (paragraphs (a) and (b) of the definition of *serious*)

Before “dentist”, insert “or a”.

12 Dictionary (paragraphs (a) and (b) of the definition of *therapeutic cannabis vaping device*)

Repeal the paragraphs, substitute:

- (a) is a vaping device, other than:
 - (i) a disposable therapeutic vape (within the meaning of the *Therapeutic Goods Regulations 1990*); or
 - (ii) a component or article imported for use in the manufacture of a therapeutic cannabis vaping device; 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 (within the meaning of that instrument) or medicines containing synthetic cannabis.

13 Dictionary (definition of *therapeutic cannabis vaping device accessory*)

Repeal the definition, substitute:

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

- (a) that is designed or intended only for use in, or with, a therapeutic cannabis vaping device; and
- (b) that is designed or intended to contain a therapeutic vaping substance; and
- (c) whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled.

14 Dictionary (definition of *therapeutic vaping device*)

Repeal the definition, substitute:

therapeutic vaping device means a therapeutic good that is a vaping device, other than:

- (a) a disposable therapeutic vape (within the meaning of the *Therapeutic Goods Regulations 1990*); or
- (b) a therapeutic cannabis vaping device.

15 Dictionary (definition of *therapeutic vaping device accessory*)

Repeal the definition, substitute:

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

- (a) that is designed or intended for use in, or with, a therapeutic vaping device; and

- (b) that is designed or intended to contain a therapeutic vaping substance; and
 - (c) whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled;
- but does not include a therapeutic cannabis vaping device accessory.

Therapeutic Goods Regulations 1990

16 Regulation 2 (paragraph (a) of the definition of *disposable therapeutic vape*)

Omit “this regulation”, substitute “subsection 41P(1) of the Act”.

17 Regulation 2 (definition of *therapeutic vaping pack*)

Repeal the definition, substitute:

therapeutic vaping pack means a primary pack that:

- (a) contains at least one therapeutic vaping substance or therapeutic vaping substance accessory; and
- (b) contains at least one therapeutic vaping device or therapeutic vaping device accessory; and
- (c) does not contain any other therapeutic goods.

18 Regulation 2 (definition of *therapeutic vaping substance accessory*)

Repeal the definition, substitute:

therapeutic vaping substance accessory means a vaping accessory that:

- (a) is designed or intended for use in, or with, a therapeutic vaping device; and
- (b) contains a therapeutic vaping substance.

19 Regulation 2 (definition of *vaping device*)

Repeal the definition.

20 After Part 2E

Insert:

Part 2F—Vaping goods

10N Commercial quantity of vaping goods

For the purposes of the definition of ***commercial quantity*** in subsection 3(1) of the Act, the commercial quantity of a kind of vaping goods specified in column 1 of an item in the following table is the quantity of that kind of vaping goods specified in column 2 of the item.

Commercial quantity of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Quantity
1	Vaping device	14
2	Vaping accessory	90

Commercial quantity of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Quantity
3	Vaping substance that is a liquid	600 ml

10P Unit of vaping goods

For the purposes of the definition of *unit* in subsection 3(1) of the Act, a *unit* of vaping goods means the quantity of the vaping goods specified in column 2 of an item in the following table for the kind of vaping goods specified in column 1 of the item.

Unit of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Unit of vaping goods
1	Vaping device	9
2	Vaping accessory	60
3	Vaping substance that is a liquid	400 ml

10Q Permitted quantity

For the purposes of the definition of *permitted quantity* in subsection 41QD(10) of the Act, the prescribed quantity of a kind of vaping goods specified in column 1 of an item in the following table is the quantity specified in column 2 of the item.

Permitted quantity of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Permitted quantity of vaping goods
1	Vaping device	2
2	Vaping accessory	4
3	Vaping substance that is a liquid	60 ml

21 After regulation 12B

Insert:

12BA Authorities for certain uses—therapeutic vaping substances that are not medicines

- (1) For the purposes of paragraph 19(6)(a) of the Act, in relation to therapeutic vaping substances that are not medicines (*authorised vaping substances*), medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.
- (2) For the purposes of subsection 19(6) of the Act, paragraph 19(6)(aa) of the Act does not apply if the supply is of an authorised vaping substance by a medical practitioner to a patient of that practitioner, where:
 - (a) the authorised vaping substance is to be administered by inhalation; and

- (b) the supply is for the indication of the treatment of smoking cessation or management of nicotine dependence.
- (3) The class of recipients prescribed for the purposes of paragraph 19(6)(b) of the Act is the class of recipients consisting of persons each of whom is seeking treatment for smoking cessation or the management of nicotine dependence.
- (4) For the purposes of subsection 19(7) of the Act, the prescribed circumstances in which an authorised vaping substance, or a class of authorised vaping substances, may be supplied in accordance with an authority under subsection 19(5) of the Act are that the supplier of the authorised vaping substance or class of authorised vaping substances complies with the treatment directions (if any) mentioned in the authority for the authorised vaping substance or class of authorised vaping substances.

22 After regulation 46A

Insert:

46B Protected persons

For the purposes of paragraph (b) of the definition of *protected person* in subsection 62(3) of the Act, a person to whom powers or functions are delegated under subsection 57(1A) of the Act is prescribed.

23 Paragraph 47A(2)(a)

Omit “registered in a State or Territory and”.

24 After regulation 47B

Insert:

47C Enforceable directions

For the purposes of paragraph 42YT(2)(e) of the Act, the following things are prescribed:

- (a) quarantine the goods;
- (b) store the goods in a secure manner;
- (c) not supply the goods.

25 Schedule 5 (table item 1, column 2, paragraph (d))

Omit “registered under a law of a State or Territory”.

26 Schedule 5A (table item 15, column 2, paragraph d))

Omit “the sponsor”, substitute “for goods other than therapeutic vaping devices, or therapeutic vaping device accessories, in a therapeutic vaping pack—the sponsor”.

27 Schedule 5A (table item 15, column 3, paragraph (b))

Repeal the paragraph, substitute:

- (b) the sponsor notice must be given as follows:
 - (i) for goods imported into Australia on or after 1 March 2024—before the goods are imported;
 - (ii) for goods imported into Australia before 1 March 2024—before the earlier of the time the goods are supplied to the ultimate consumer and the end of the period of 2 months beginning

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- on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences; and
- (iii) for goods manufactured in Australia on or after 1 March 2024—before the goods are first supplied in Australia; and
 - (iv) for goods manufactured in Australia before 1 March 2024—before the earlier of the time the goods are supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences; and

28 Schedule 5A (table item 15, column 3, paragraphs (g) and (h))

Repeal the paragraphs, substitute:

- (fa) the sponsor must:
 - (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the goods; 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
- (fb) the sponsor must allow an authorised officer:
 - (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the goods; and
 - (ii) while on those premises, to inspect those premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on those premises that relates to the goods; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
- (fc) the sponsor must, if requested to do so by an authorised officer, produce to the authorised officer such documents relating to the goods as the authorised officer requires and allow the authorised officer to copy the documents; and
- (fd) if the sponsor is not the manufacturer of the goods, the sponsor must have procedures in place to ensure that the manufacturer of the goods allows an authorised officer:
 - (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the goods; and
 - (ii) while on those premises, to inspect those premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on those premises that relates to the goods; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
- (fe) if the sponsor is not the manufacturer of the goods, the sponsor must have procedures in place to ensure that the manufacturer of the goods, if the manufacturer is requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised officer requires and allow the authorised officer to copy the documents; and
- (g) for goods manufactured in Australia—either of the following apply:
 - (i) the goods are manufactured by a person who is the holder of a licence in force under Part 3-3 of the Act that authorises the manufacture of the goods, or the carrying out of the step in the manufacture of the goods, at the manufacturing site where the manufacture, or the step, is carried out;
 - (ii) the goods are manufactured by 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 the Secretary has given the person a consent under subsection 41RC(1) of the Act to manufacture the goods, or carry out the step in the manufacture of the goods, and the manufacture, or the step, is carried out in accordance with the consent; and
- (h) the goods may be supplied to a person who is not the ultimate consumer of the goods only if:
 - (i) the person (the **recipient**) to whom the goods are supplied is the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods; or
 - (ii) 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 1 Main amendments

Part 1 Amendments

- 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
- (iii) the Secretary has given the recipient a consent under subsection 41RC(1) of the Act to supply the goods; or
 - (iv) in the case of goods that are covered by a determination made by the Minister under section 41R of the Act—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods; and

29 Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Repeal the subparagraph, substitute:

- (ii) the supply is by 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 recipient carries on a business, practises or is employed; and

30 Schedule 5A (table item 15, column 3, subparagraph (i)(iii))

Omit “the supply”, substitute “for goods other than therapeutic vaping devices, or therapeutic vaping device accessories, in a therapeutic vaping pack—the supply”.

31 Schedule 5A (table item 16, column 3, after paragraph (b))

Insert:

(ba) the sponsor must:

- (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the goods; 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

32 Schedule 7 (table items 22 and 23, column 2, subparagraph (a)(iii))

Omit “registered under a law of a State or Territory”.

Part 2—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

33 Regulation 11.73

Omit “on or after”, substitute “before, on or after”.

34 In the appropriate position in Part 11

Insert:

Division 11.22—Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

11.79 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

11.80 Application of amendments

- (1) The amendment made by item 3 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule.
- (2) The amendments made by items 4 and 5 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule.
- (3) The amendments made by items 6 and 7 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported on or after 1 October 2024.
- (4) The amendment made by item 8 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule.
- (5) The amendment made by item 12 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after 1 October 2024.

11.81 Transitional vaping devices—exemption from Division 3 of Part 4-11 of the Act

- (1) For the purposes of this regulation, medical devices that are exported from Australia are *transitional vaping devices* if:
 - (a) the devices are therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods; and
 - (b) the devices were imported into, or manufactured in, Australia before the commencement of Schedule 1 to the amending regulations; and

- (c) as at that commencement, the importation or manufacture, or any supply, of the devices was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

Exemption

- (2) For the purposes of paragraph 41HA(1)(b) of the Act, transitional vaping devices are exempt from the operation of Division 3 of Part 4-11 of the Act.

When exemption ceases

- (3) Subregulation (2) ceases to have effect at the end of the period of 6 months starting on the day Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commence.

Therapeutic Goods Regulations 1990

35 Subregulation 96(5)

Omit “on or after”, substitute “before, on or after”.

36 In the appropriate position in Part 9

Insert:

Division 26—Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

104 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

105 Authorities for therapeutic vaping substances that are not medicines

Regulation 12BA, as inserted by Schedule 1 to the amending regulations, applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Schedule.

106 Therapeutic vaping packs

The amendment made by item 17 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured on or after 1 October 2024.

107 Exempt goods

- (1) The amendment made by item 27 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule.

- (2) The amendments made by items 26 and 28 to 30 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule.
- (3) The amendment made by item 31 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule.

108 Transitional vaping goods—exemption from Part 3-2 of the Act

- (1) For the purposes of this regulation, therapeutic goods that are exported from Australia are *transitional vaping goods* if:
 - (a) the goods are therapeutic vaping goods; and
 - (b) the goods were imported into, or manufactured in, Australia before the commencement of Schedule 1 to the amending regulations; and
 - (c) as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

Exemption

- (2) For the purposes of subsection 18(1) of the Act, transitional vaping goods are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F).

When exemption ceases

- (3) Subregulation (2) ceases to have effect at the end of the period of 6 months starting on the day Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commence.

Schedule 2—Commercial quantities

Therapeutic Goods Regulations 1990

1 Regulation 10N (table)

Repeal the table, substitute:

Unit of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Unit of vaping goods
1	Vaping device	9
2	Vaping accessory	60
3	Vaping substance that is a liquid	400 ml

Schedule 3—Other amendments

Therapeutic Goods Regulations 1990

1 After paragraph 3(3)(bab)

Insert:

(bac) the *Therapeutic Goods Law Application Act 2024* (WA);