



Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 12 December 2024

Sam Mostyn AC
Governor-General

By Her 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—Amendments		2
Part 1—Main amendments		2
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		2
<i>Therapeutic Goods Regulations 1990</i>		4
Part 2—Transitional provisions		6
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		6
<i>Therapeutic Goods Regulations 1990</i>		7

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) 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. The whole of this instrument	The day after this instrument is registered.	14 December 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Amendments

Part 1—Main amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Paragraph 10.7(1A)(c)

Omit ‘paragraph (e) of the column headed “Conditions”’, substitute ‘paragraph (d) of the column headed “Kinds of medical devices”’.

2 Part 2 of Schedule 4 (cell at table item 2.17, column headed “Kinds of medical devices”)

Repeal the cell, substitute:

Medical device, if:

- (a) the device is:
 - (i) a therapeutic vaping device; or
 - (ii) a therapeutic vaping device accessory; and
- (b) the sponsor has given the Secretary a notice (the *sponsor notice*) 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; and
- (c) the sponsor notice has not been withdrawn by the sponsor by a notice (the *withdrawal notice*) given to the Secretary, with the withdrawal taking effect:
 - (i) on the day specified in the withdrawal notice, being a day that is later than the day that notice is given to the Secretary; or
 - (ii) otherwise—on the day the withdrawal notice is given; and
- (d) 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 compromises public health and safety; or
- (ii) the Secretary is satisfied that the device does not comply with the essential principles; or
- (iii) the sponsor has failed to comply with a request by the Secretary under paragraph (e) of the column headed “Conditions” of this item

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

Repeal the paragraph, substitute:

- (a) The sponsor must give the sponsor notice to the Secretary in a form approved in writing by the Secretary.

4 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraphs (c) to (e))

Repeal the paragraphs, substitute:

- (c) The sponsor holds information or evidence to support:
 - (i) the statement made in the sponsor notice under subparagraph (b)(i) of the column headed “Kinds of medical devices” of this item; and
 - (ii) if the sponsor has not given a notice under paragraph (e) of this column of this item—the statement made in the sponsor notice under subparagraph (b)(ii) of the column headed “Kinds of medical devices” of this item; and
 - (iii) if the sponsor has given one or more notices under paragraph (e) of this column of this item—the statement made in the most recent of those notices;

including, in relation to a statement that the device complies with the essential principles, to demonstrate ongoing compliance with the essential principles.

- (d) The following statements are, and continue to be, correct:
 - (i) the statement made in the sponsor notice under subparagraph (b)(i) of the column headed “Kinds of medical devices” of this item;
 - (ii) if the sponsor has not given a notice under paragraph (e) of this column of this item—the statement made in the sponsor notice under subparagraph (b)(ii) of the column headed “Kinds of medical devices” of this item;
 - (iii) if the sponsor has given one or more notices under paragraph (e) of this column of this item—the statement made in the most recent of those notices;

including, in relation to a statement that the device complies with the essential principles, that the device continues to comply with the essential principles.

- (e) The sponsor must:
 - (i) if requested by the Secretary, give the Secretary a notice, in a form approved in writing by the Secretary, stating either that the device complies with the essential principles or that the device is being imported or supplied (as the case may be) with the consent of the Secretary under section 41MA or 41MAA of the Act; 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).

5 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraphs (fb) to (fe))

Omit “authorised officer” (wherever occurring), substitute “authorised person”.

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

Omit “the records”, substitute “a copy of the records”.

7 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, at the end of paragraph (i))

Add:

- ; and (iii) if the Secretary requests information about the supply of the device during a specified period—give the information 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 in a form approved in writing by the Secretary.

Therapeutic Goods Regulations 1990

8 Regulation 10N (table heading)

Omit “Unit” (first occurring), substitute “Commercial quantity”.

9 Regulation 10N (table, heading to column 2)

Omit “Unit of vaping goods”, substitute “Quantity”.

10 Paragraph 48(1AB)(c)

Omit “paragraph (e) of column 3”, substitute “paragraph (g) of column 2”.

11 Schedule 5A (at the end of the cell at table item 15, column 2)

Add:

- ; and (e) the sponsor has given the Secretary a notice (the *sponsor notice*) stating that:
- (i) the goods conform with each standard (as in force from time to time) that is 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
- (f) the sponsor notice has not been withdrawn by the sponsor by a notice (the *withdrawal notice*) given to the Secretary, with the withdrawal taking effect:
- (i) on the day specified in the withdrawal notice, being a day that is later than the day that notice is given to the Secretary; or
 - (ii) otherwise—on the day the withdrawal notice is given; and
- (g) 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 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; or
 - (iii) the sponsor has failed to comply with a request by the Secretary under paragraph (e) of column 3 of this item

12 Schedule 5A (table item 15, column 3, paragraph (a))

Repeal the paragraph, substitute:

- (a) the sponsor must give the sponsor notice to the Secretary in a form approved in writing by the Secretary; and

13 Schedule 5A (table item 15, column 3, paragraphs (c) to (e))

Repeal the paragraphs, substitute:

- (c) the sponsor holds information or evidence to support:
- (i) the statement made in the sponsor notice under subparagraph (e)(ii) of column 2 of this item; and
 - (ii) if the sponsor has not given a notice under paragraph (e) of this column of this item—the statement made in the sponsor notice under subparagraph (e)(i) of column 2 of this item; and
 - (iii) if the sponsor has given one or more notices under paragraph (e) of this column of this item—the statement made in the most recent of those notices;
- including, in relation to a statement that the goods conform with each standard (as in force from time to time) that is applicable to the goods, to demonstrate that the goods continue to so conform; and
- (d) the following statements are, and continue to be, correct:
- (i) the statement made in the sponsor notice under subparagraph (e)(ii) of column 2 of this item;
 - (ii) if the sponsor has not given a notice under paragraph (e) of this column of this item—the statement made in the sponsor notice under subparagraph (e)(i) of column 2 of this item;
 - (iii) if the sponsor has given one or more notices under paragraph (e) of this column of this item—the statement made in the most recent of those notices;
- including, in relation to a statement that the goods conform with each standard (as in force from time to time) that is applicable to the goods, that the goods continue to so conform; and
- (e) the sponsor must:
- (i) if requested by the Secretary, give the Secretary a notice, in a form approved in writing by the Secretary, stating either that the goods conform with each standard (as in force from time to time) that is applicable to the goods or that the goods are being imported or supplied (as the case may be) with the consent of the Secretary under section 14 or 14A of the Act; 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

14 Schedule 5A (table item 15, column 3, subparagraph (j)(ii))

Omit “the records”, substitute “a copy of the records”.

15 Schedule 5A (table item 15, column 3, at the end of paragraph (j))

Add:

- (iii) if the Secretary requests information about the supply of the goods during a specified period—give the information 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 in a form approved in writing by the Secretary; and

Part 2—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

16 In the appropriate position in Part 11

Insert:

Division 11.23—Application, transitional and saving provisions relating to the Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024

11.82 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*.

commencement day means the day this Division commences.

conditions column means the column headed “Conditions” in the table in Part 2 of Schedule 4.

devices column means the column headed “Kinds of medical devices” in the table in Part 2 of Schedule 4.

11.83 Exempt therapeutic goods

- (1) Subject to this regulation, the amendments of these Regulations made by Part 1 of Schedule 1 to the amending regulations apply in relation to therapeutic goods that are:
 - (a) imported or manufactured on or after the commencement day; or
 - (b) for therapeutic goods owned by, or in the possession or control of, the sponsor immediately before the commencement day—supplied on or after the commencement day.
- (2) The substitution of paragraph (c) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, made by Part 1 of Schedule 1 to the amending regulations, applies in relation to information or evidence held by the sponsor on or after the commencement day.
- (3) Paragraph (e) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, as substituted by Part 1 of Schedule 1 to the amending regulations, applies in relation to a request made by the Secretary under that paragraph on or after the commencement day.
- (4) The amendment to subparagraph (i)(ii) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, made by Part 1 of Schedule 1 to the amending regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.
- (5) Subparagraph (i)(iii) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4, as added by Part 1 of Schedule 1 to the amending regulations,

applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

11.84 Notices, statements and determinations

(1) A notice:

- (a) given before the commencement day, under paragraph (a) (the *old provision*) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4 as in force immediately before that day; and
- (b) not withdrawn or otherwise ceased to have effect (however described) before the commencement day;

has effect on and after the commencement day as if it had been given under paragraph (b) (the *new provision*) of the devices column in that item (and a statement given in the notice under a subparagraph of the old provision has effect on and after the commencement day as if it had been given under the corresponding subparagraph of the new provision).

(2) A determination by the Secretary:

- (a) as referred to in paragraph (e) of the conditions column in item 2.17 of the table in Part 2 of Schedule 4 as in force immediately before that day; and
- (b) in force immediately before the commencement day;

has effect on and after the commencement day as if it were a determination referred to in paragraph (d) of the devices column in that item.

Therapeutic Goods Regulations 1990

17 In the appropriate position in Part 9

Insert:

Division 27—Application, transitional and saving provisions relating to the Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024

109 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 3) Regulations 2024*.

commencement day means the day this Division commences.

110 Exempt therapeutic goods

- (1) Subject to this regulation, the amendments of paragraph 48(1AB)(c), and item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the amending regulations, apply in relation to therapeutic goods that are:
 - (a) imported or manufactured on or after the commencement day; or
 - (b) for therapeutic goods owned by, or in the possession or control of, the sponsor immediately before the commencement day—supplied on or after the commencement day.

- (2) The substitution of paragraph (c) of column 3 in item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the amending regulations, applies in relation to information or evidence held by the sponsor on or after the commencement day.
- (3) Paragraph (e) of column 3 in item 15 of the table in Schedule 5A, as substituted by Part 1 of Schedule 1 to the amending regulations, applies in relation to a request made by the Secretary under that paragraph on or after the commencement day.
- (4) The amendment to subparagraph (j)(ii) of column 3 in item 15 of the table in Schedule 5A, made by Part 1 of Schedule 1 to the amending regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.
- (5) Subparagraph (j)(iii) of column 3 in item 15 of the table in Schedule 5A, as added by Part 1 of Schedule 1 to the amending regulations, applies in relation to a request made by the Secretary under that subparagraph on or after the commencement day.

111 Notices, statements and determinations

- (1) A notice:
 - (a) given before the commencement day, under paragraph (a) (the *old provision*) of column 3 in item 15 of the table in Schedule 5A as in force immediately before that day; and
 - (b) not withdrawn or otherwise ceased to have effect (however described) before the commencement day;has effect on and after the commencement day as if it had been given under paragraph (e) (the *new provision*) of column 2 in that item (and a statement given in the notice under a subparagraph of the old provision has effect on and after the commencement day as if it had been given under the corresponding subparagraph of the new provision).
- (2) A determination by the Secretary:
 - (a) as referred to in paragraph (e) of column 3 in item 15 of the table in Schedule 5A as in force immediately before that day; and
 - (b) in force immediately before the commencement day;has effect on and after the commencement day as if it were a determination referred to in paragraph (g) of column 2 in that item.