



Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024

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 29 February 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.....	1
Schedule 1—Amendments		2
Part 1—Main amendments		2
<i>Therapeutic Goods Regulations 1990</i>		2
Part 2—Transitional provisions		4
<i>Therapeutic Goods Regulations 1990</i>		4

1 Name

This instrument is the *Therapeutic Goods Amendment (2024 Measures No. 1) 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	1 March 2024.	1 March 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Regulations 1990

1 Schedule 5A (table item 1)

Repeal the item, substitute:

- 1 Therapeutic goods imported into Australia, if:
- (a) the goods are not any of the following:
 - (i) disposable therapeutic vapes (other than disposable therapeutic vapes that are, or include, medicinal cannabis products);
 - (ii) therapeutic vaping substances (other than therapeutic vaping substances that are medicinal cannabis products);
 - (iii) therapeutic vaping substance accessories (other than therapeutic vaping substance accessories that are, or include, medicinal cannabis products);
 - (iv) a therapeutic vaping kit (other than a therapeutic vaping kit where each good in the kit is, or includes, a medicinal cannabis product);
 - (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
- (a) the supply of the goods must be in accordance with the relevant notification, approval, authorisation or prescription; and
 - (b) the goods must be kept in a warehouse or a properly secured area under the control of the sponsor; and
 - (c) 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

- (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

Part 2—Transitional provisions

Therapeutic Goods Regulations 1990

2 In the appropriate position in Part 9

Insert:

Division 24—Application provision relating to the Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024

98 Exempt goods

The amendment of item 1 of the table in Schedule 5A to these Regulations made by Schedule 1 to the *Therapeutic Goods Amendment (2024 Measures No. 1) Regulations 2024* applies in relation to therapeutic goods imported on or after 1 March 2024.