

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

Therapeutic Goods Regulations 1990 2

Part 2—Transitional provisions 4

Therapeutic Goods Regulations 1990 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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  (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 | (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 |

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.