

Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019

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 19 September 2019

David Hurley

Governor‑General

By His Excellency’s Command

Greg Hunt

Minister for Health

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1 Name

This instrument is the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019*.

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. | 26 September 2019 |

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods Regulations 1990

1 Paragraph 43A(4)(d)

Omit “within the period of 18 months beginning on 6 March 2018”, substitute “before the end of 5 March 2021”.

2 In the appropriate position in Part 9

Insert:

Division 11—Application and transitional provisions relating to the Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019

68 Application and transitional provisions

(1) The amendment of regulation 43A made by the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019* applies in relation to applications made on or after 6 September 2019.

(2) If, on or after 6 September 2019 and before the commencement of the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019*, a person:

(a) made an application for the listing of medicine in circumstances where paragraphs 43A(4)(a) to (c) were satisfied; and

(b) paid the fee under paragraph (b) of item 3 of the table in Part 2 of Schedule 9 in relation to the application;

the Secretary must, on behalf of the Commonwealth, refund to the person an amount equal to the fee paid.