



## **Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019**

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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