Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021

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 15 April 2021

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021*.

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. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	17 April 2021
2. Schedule 1, items 1 and 2	At the same time as Schedules 5 and 6 to the *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* commence.	19 April 2021
3. Schedule 1, item 3	The day after this instrument is registered.	17 April 2021
4. Schedule 2	The day after this instrument is registered.	17 April 2021

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods Regulations 1990

1 After regulation 15

Insert:

15AA Clinical trial registries

For the purposes of subparagraph 26AF(2)(b)(ii) of the Act, the following registries are prescribed:

(a) a primary registry that at any time is in the World Health Organisation's International Clinical Trials Registry Platform, as the registry exists from time to time;

(b) the database known as ClinicalTrials.gov, as the database exists from time to time.

2 After regulation 16GI

Insert:

16GIA Period for paying evaluation fee for application under subsection 26BD(1) of the Act

For the purposes of paragraph 26BDA(c) of the Act, the period is the period of 2 months beginning on the day that the applicant is notified of the amount of the evaluation fee and of the requirement for that fee to be paid.

3 Regulation 43AAGG

Omit "For section 44A", substitute "For the purposes of paragraph 63(3)(b)".

Schedule 2—Amendments of Therapeutic Goods (Medical Devices) Regulations

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulation 11.51(3)

Repeal the subregulation, substitute:

(3) Item 2.14 of the table in Part 2 of Schedule 4, as added by Schedule 3 to the amending regulations, applies in relation to a patient-matched medical device if it is manufactured on or after 25 February 2021 and before 1 November 2024.

2 Part 2 of Schedule 4 (table item 2.14)

Omit "each kind of medical device covered by the description mentioned in paragraph 11.51(3)(b)", substitute "each kind of patient-matched medical device".