Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023

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 23 November 2023

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

OPC66538 - A

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023*.

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.	28 November 2023
2. Schedule 1, Parts 1 to 4	The day after this instrument is registered.	28 November 2023
3. Schedule 1, Part 5	1 January 2024.	1 January 2024
4. Schedule 1, Part 6	The day after this instrument is registered.	28 November 2023

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subregulation 11.40(2)

Omit all the words after "transitional medical device", substitute:

on and after:

(a) for a transitional AIMD device—1 November 2024; and

(b) for a transitional medical device other than a transitional AIMD device—1 July 2029.

2 Subparagraph 11.40(3)(a)(iii)

Repeal the subparagraph, substitute:

(iii) before the day mentioned in paragraph (2)(a) or (b) (as the case may be) for the transitional medical device;

3 Subregulations 11.51(3) and 11.52(2)

Omit "1 November 2024", substitute "1 July 2029".

4 Subparagraph 11.52(3)(a)(iii)

Omit "1 November 2024", substitute "1 July 2029".

5 Part 2 of Schedule 4 (table item 2.14, column headed "Conditions")

Omit "25 August 2022", substitute "1 November 2024".

6 Part 2 of Schedule 4 (table item 2.14, column headed "Conditions")

Omit "1 November 2024", substitute "1 July 2029".

Part 2—Clinical trials

Therapeutic Goods (Medical Devices) Regulations 2002

7 Subregulation 7.4(1)

Omit "For subparagraph 7.3(2)(b)(ii) and subject to subregulation (2), an authorised person may do any of the following things in relation to a clinical trial of a kind of medical device that has been approved for use solely for experimental purposes in humans", substitute "Subject to subregulation (2), an authorised person may do any of the following things in relation to a clinical trial mentioned in regulation 7.3 or in item 2.3 of the table in Part 2 of Schedule 4".

8 Paragraphs 7.4(1)(b), (c) and (d)

Omit "anything", substitute "any thing".

9 Paragraph 7.4(1)(e)

Repeal the paragraph.

10 At the end of subregulation 7.4(1)

Add:

Note: To avoid doubt, a reference to a thing in paragraph (b), (c) or (d) includes a reference to a book, record or document.

11 In the appropriate position in Part 11

Insert:

Division 11.18—Application provisions relating to the Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023

11.72 Clinical trials

(1) The amendments of subregulation 7.4(1) of these Regulations made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* apply in relation to things done on or after the commencement of those amendments in relation to a clinical trial that began before, on or after that commencement.

(2) The amendment of Schedule 4 to these Regulations made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* applies in relation to:

(a) requests made on or after the commencement of that amendment to give information acquired before, on or after that commencement; and

(b) things mentioned in regulation 7.4 of these Regulations done on or after that commencement;

in relation to a clinical trial that began before, on or after that commencement.

12 Part 2 of Schedule 4 (at the end of the cell at table item 2.3, column headed "Conditions")

Add:

(i) The sponsor must comply with requests by an authorised person, whether made before or after the start of the trial, to give information about the conduct of the trial (whether or not the sponsor is conducting the trial).

(j) If a body or organisation is conducting the trial for the sponsor, that body or organisation must comply with requests by an authorised person, whether made before or after the start of the trial, to give information about the conduct of the trial.

(k) The sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must allow an authorised person to do the things mentioned in regulation 7.4.

(l) The sponsor must:

(i) if requested in writing by the Secretary, give the Secretary specified information or documents relating to the safety or performance of the medical device covered by the trial; and

(ii) do so within 14 days of receiving the request or such longer period (if any) allowed in writing by the Secretary.

Therapeutic Goods Regulations 1990

13 Paragraph 12AC(1)(e)

Repeal the paragraph.

14 At the end of subregulation 12AC(1)

Add:

Note: To avoid doubt, a reference to a thing in paragraph (b), (c) or (d) includes a reference to a book, record or document.

15 In the appropriate position in Part 9

Insert:

Division 22—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023

91 Clinical trials

The amendments of subregulation 12AC(1) of these Regulations made by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* apply in relation to things done on or after the commencement of those amendments in relation to a clinical trial that began before, on or after that commencement.

16 Schedule 5A (table item 3, column 3, paragraph (h))

Omit "any", substitute "either or both".

Part 3—Authorised prescriber scheme

Therapeutic Goods Regulations 1990

17 Subregulation 12B(1C) (at the end of the cell at table item 1, column 5)

Add:

; or (c) treatment of refractory sleep disorders in adult patients; or

(d) treatment of autism spectrum disorder in adult patients; or

(e) treatment and management of refractory cancer pain in adult patients

18 Subregulation 12B(1C) (after table item 1)

Insert:

1A	(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and (b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and (c) the medicine contains no other active ingredients	spray	oral	treatment of refractory chronic pain in adult patients

19 Subregulation 12B(1C) (at the end of the cell at table item 3, column 5)

Add:

; or (c) treatment of refractory sleep disorders in adult patients; or

(d) treatment and management of refractory cancer pain in adult patients

20 Subregulation 12B(1C) (cell at table item 5, column 5)

Repeal the cell, substitute:

(a) treatment of refractory chronic pain in adult patients; or

(b) treatment of refractory sleep disorders in adult patients; or

(c) treatment and management of refractory cancer pain in adult patients

Part 4—Fees for certain vaccine strains updates

Therapeutic Goods Regulations 1990

21 Clause 3 of Schedule 9 (after paragraph (bca) of table item 2)

Insert:

(bcb) for an application relating to a medicine in relation to which an evaluation fee is payable under paragraph (ac) of item 4	1,241

22 Clause 3 of Schedule 9 (table item 4, column 2, paragraph (a))

Omit "or (ab)", substitute ", (ab) or (ac)".

23 Clause 3 of Schedule 9 (after paragraph (ab) of table item 4)

Insert:

(ac) a vaccine for COVID-19, respiratory syncytial virus (RSV) or influenza that is a new chemical entity, if: (i) the vaccine is a new chemical entity only because the vaccine is for a new strain; and (ii) the vaccine is a closely related form of an existing vaccine, for another strain, in the Register in relation to which the applicant is the sponsor	4,954

Part 5—Removal of exemptions for sunscreen preparations

Therapeutic Goods Regulations 1990

24 Paragraph 49(a)

Repeal the paragraph.

25 Paragraph 49(b)

After "continues to apply", insert "until the end of 31 December 2026".

26 Paragraph 49(b)

Omit "that date", substitute "9 November 2012".

27 Paragraph 49(c)

After "continues to apply", insert "until the end of 31 December 2026".

28 Paragraph 49(c)

Omit "that date", substitute "9 November 2012".

29 At the end of Division 22 of Part 9

Add:

92 Removal of exemptions for sunscreen preparations

Despite the amendments of Schedules 5 and 7 to these Regulations made by Part 5 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023*:

(a) paragraph (g) of item 8 of Schedule 5 to these Regulations, as in force immediately before the commencement of those amendments, continues to apply until the end of 31 December 2026 in relation to therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act immediately before that commencement; and

(b) item 14 of Schedule 7 to these Regulations, as in force immediately before the commencement of those amendments, continues to apply until the end of 31 December 2026 in relation to therapeutic goods exempt from the operation of Part 3-3 of the Act immediately before that commencement.

30 Schedule 5 (table item 8, paragraph (f))

Omit "Schedule 4;", substitute "Schedule 4".

31 Schedule 5 (table item 8, paragraph (g))

Repeal the paragraph.

32 Schedule 7 (table item 14)

Repeal the table item.

Part 6—Minor amendments

Therapeutic Goods (Medical Devices) Regulations 2002

33 Subregulation 10.7(1) (paragraph (b) of the definition of *initial decision*)

Repeal the paragraph.

Therapeutic Goods Regulations 1990

34 Schedule 4 (table item 8)

Omit "where", substitute "to be listed under section 26AE of the Act, if".