

Therapeutic Goods Legislation Amendment (2021 Measures No. 4) 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 16 December 2021

David Hurley

Governor‑General

By His Excellency’s Command

Greg Hunt

Minister for Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) 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. | 18 December 2021 |
| 2. Schedule 1, Part 1 | The day after this instrument is registered. | 18 December 2021 |
| 3. Schedule 1, Part 2, Division 1 | The day after this instrument is registered. | 18 December 2021 |
| 4. Schedule 1, Part 2, Division 2 | 1 January 2022. | 1 January 2022 |

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 In the appropriate position in Part 11

Insert:

Division 11.14—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021

11.67 Patient implant cards and patient information leaflets

The amendments of clause 13A.1 of Schedule 1 made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to a medical device that is imported, supplied or exported on or after the commencement of that Part.

2 Clause 13A.1 of Schedule 1

Before “Clauses”, insert “(1)”.

3 At the end of clause 13A.1 of Schedule 1

Add:

; and (c) not a medical device to which subclause (2) applies.

(2) This subclause applies to a medical device if:

(a) the medical device is intended by the manufacturer to be wholly, or mostly, absorbed by a patient’s body within 6 months of being implanted; and

(b) the medical device is:

(i) for use as a filler; or

(ii) for haemostasis; or

(iii) for tissue approximation; or

(iv) for the fixation of other medical devices within tissue; or

(v) a similar medical device to a medical device covered by subparagraph (i), (ii), (iii) or (iv).

4 Part 2 of Schedule 4 (table item 2.16, column headed “Kinds of medical devices”, subparagraph (c)(ii))

Omit “Class I medical devices”, substitute “Class I, Class IIa, Class IIb or Class III medical devices”.

Part 2—Other amendments

Division 1—Amendments commencing on day after registration

Therapeutic Goods Regulations 1990

5 Paragraph 7(g)

After “Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*”, insert “(except items 2.12, 2.13, 2.14 and 2.15 of that Part)”.

6 Subregulation 12B(1B) (cell at table item 45A, column 4)

Repeal the cell, substitute:

|  |
| --- |
| ophthalmic |

7 Subregulation 12B(1B) (cell at table item 46B, column 2)

Repeal the cell, substitute:

|  |
| --- |
| lutetium‑177 (Lu 177) prostate specific membrane antigen (PSMA) |

8 Subregulation 12B(1B) (cell at table item 72A, column 2)

Repeal the cell, substitute:

|  |
| --- |
| Technetium‑99m (99m Tc) prostate specific membrane antigen (PSMA)**‑**I&S |

9 In the appropriate position in Part 9

Insert:

Division 17—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021

84 Amendments made by Division 1 of Part 2 of Schedule 1

(1) The amendment of paragraph 7(g) made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* applies in relation to an advertisement that is made on or after the commencement of that amendment.

(2) The amendment of item 1B of the table in Schedule 5A made by Division 1 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* applies in relation to therapeutic goods imported into Australia on or after the commencement of that amendment.

10 Schedule 5A (table item 1B, column 3, paragraph (a))

Repeal the paragraph, substitute:

|  |
| --- |
| (a) the goods must be supplied to a person covered by column 2 in circumstances where subparagraphs 12A(2)(a)(ii) and (iii) and paragraph 12A(2)(b) of these Regulations are satisfied; and |

Division 2—Amendments commencing on 1 January 2022

Therapeutic Goods Regulations 1990

11 Subregulation 6B(1)

Repeal the subregulation, substitute:

Prohibited representations

(1) For the purposes of subsection 42DJ(1) of the Act:

(a) the representations in column 2 of an item in the table in Part 1 of Schedule 2 are specified; and

(b) the therapeutic goods in column 3 of that item are specified.

Note: Under subsection 42DJ(1) of the Act, those representations about those goods are prohibited representations.

12 Before subregulation 6B(2)

Insert:

Required representations

13 Regulation 8

Omit “sections 9, 10, 15, 16, 18, 19 and 21”, substitute “sections 8, 9, 10, 11, 12, 24 (to the extent that it relates to endorsements) and 26”.

14 Regulation 8 (note)

Omit “section 6”, substitute “sections 5 and 6”.

15 At the end of Division 17 of Part 9

Add:

85 Amendments made by Division 2 of Part 2 of Schedule 1

(1) The amendments of regulation 6B and of Part 1 of Schedule 2 made by Division 2 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to an advertisement that is made on or after the commencement of those amendments.

(2) The amendments of regulation 8 made by Division 2 of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 4) Regulations 2021* apply in relation to the dissemination of generic information on or after the commencement of those amendments.

16 Part 1 of Schedule 2 (table item 4)

Repeal the item, substitute:

|  |  |  |
| --- | --- | --- |
| 4 | a representation that states or implies that:  (a) analgesic consumption is safe; or  (b) analgesics will relax, relieve tension, sedate or stimulate | analgesics |

17 Part 1 of Schedule 2 (table item 8)

Repeal the item, substitute:

|  |  |  |
| --- | --- | --- |
| 8 | a representation that states or implies that vitamin or mineral supplements:  (a) are a substitute for good nutrition or a balanced diet; or  (b) are in any way superior to or more beneficial than dietary nutrients | vitamin or mineral supplements |

18 Part 1 of Schedule 2 (at the end of the table)

Add:

|  |  |  |
| --- | --- | --- |
| 10 | The following:  (a) a representation regarding abortifacient action;  (b) a representation regarding the treatment, cure, prevention, diagnosis (including screening) or monitoring of, or the susceptibility or pre‑disposition to, one or more of the following:  (i) neoplastic disease;  (ii) sexually transmitted diseases;  (iii) human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS);  (iv) hepatitis C virus (HCV);  (v) mental illness | all therapeutic goods |