



## **Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022**

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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 15 December 2022

David Hurley  
Governor-General

By His Excellency's Command

Mark Butler  
Minister for Health and Aged Care

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## 1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022*.

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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

### *Therapeutic Goods (Medical Devices) Regulations 2002*

#### 1 Subparagraph 9.1AA(3)(b)(iii)

Omit “European Union; and”; substitute “European Union;”.

#### 2 At the end of paragraph 9.1AA(3)(b)

Add:

- (iv) ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*, published by the International Organization for Standardization; and

#### 3 Paragraph 9.1AA(3)(c)

Repeal the paragraph, substitute:

- (c) a new overseas regulator conformity assessment document has been issued, or is expected to be issued, in respect of devices of that kind under one of the following:
  - (i) Regulation 2017/745 (as in force from time to time) of the European Parliament and the Council of the European Union;
  - (ii) Regulation 2017/746 (as in force from time to time) of the European Parliament and the Council of the European Union;
  - (iii) the Medical Device Single Audit Program (within the meaning of the *Therapeutic Goods (Overseas Regulators) Determination 2018*).

#### 4 In the appropriate position in Part 11

Insert:

### **Division 11.16—Application provisions relating to the Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022**

#### **11.69 Fee for application for consent of Secretary**

- (1) The amendments of regulation 9.1AA made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* apply in relation to an application for consent that is made on or after the commencement of this regulation.
- (2) If:
  - (a) on or after 1 January 2022 and before the commencement of this regulation, a person made an application of a kind covered by paragraph (a) or (b) of item 1.15 of the table in Part 1 of Schedule 5; and
  - (b) the application was made in relation to the application of one or more of clauses 13.1 to 13.4 of Schedule 1 to the medical device or devices; and
  - (c) the reason for the medical device or devices not complying with one or more of those clauses was that the device or devices were affected by the EU transition (within the meaning of subregulation 9.1AA(3) of these Regulations as in force at the commencement of this regulation); and

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- (d) the application was made:
    - (i) solely in relation to the application of one or more of those clauses; or
    - (ii) also in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1, but not any other provision; and
  - (e) on or after 1 January 2022 and before the commencement of this regulation, the person paid the fee applicable in relation to the application under item 1.15 of the table in Part 1 of Schedule 5;

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the application under regulation 9.1AA if the application had been made on the day on which this regulation commences.

### **11.70 Exempt medical devices**

The amendment of Schedule 4 made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* applies in relation to a medical device that is imported into Australia on or after the commencement of this regulation.

### **5 After clause 7.6 of Schedule 1**

Insert:

#### **7.7 Minimisation of risks associated with nanomaterials**

- (1) A medical device must be designed and produced in a way that ensures that any risks associated with the size and the properties of particles which are, or can be, released into a patient's or user's body are minimised.
- (2) In minimising risks, particular attention must be given to the use of nanomaterials.
- (3) Subclause (1) does not apply to particles that come into contact with intact skin only.

### **6 After paragraph 13A.1(1)(b) of Schedule 1**

Insert:

- (ba) not intended by the manufacturer to be for export only; and

### **7 Schedule 4 (table item 1.1, column headed "Kinds of medical devices", paragraph (c))**

Repeal the paragraph, substitute:

- (c) in the case of a Class 4 IVD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device or Class IIa medical device:
  - (i) the quantity imported in one importation is not more than the amount required to give 3 months use of the device according to:
    - (A) the treating medical practitioner's directions; or
    - (B) the manufacturer's instructions for use of the device; or
    - (C) directions, recommendations or advice of a Commonwealth, State or Territory authority that has functions in relation to, or that is responsible for or deals with, health matters; and
  - (ii) the total quantity imported in a 12 month period is not more than the

- amount required to give 15 months use of the device according to:
- (A) the treating medical practitioner's directions; or
  - (B) the manufacturer's instructions for use of the device; or
  - (C) directions, recommendations or advice of a Commonwealth, State or Territory authority that has functions in relation to, or that is responsible for or deals with, health matters; and

## **8 Dictionary**

Insert:

*nanomaterial* has the meaning given by Article 2(18) of Regulation 2017/745 (as in force from time to time) of the European Parliament and the Council of the European Union.



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## Schedule 2—Amendments relating to medicines and fees

### *Therapeutic Goods Regulations 1990*

#### **1 Regulation 2 (definition of *IN1 application*)**

Repeal the definition, substitute:

***IN1 application*** means an application made under subsection 26BD(1) of the Act for a recommendation to vary a section 26BB determination, if the variation is of a kind that requires:

- (a) an evaluation of the safety and quality of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; or
- (b) an evaluation of:
  - (i) the safety of an ingredient based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction determined under regulation 16GJ; and
  - (ii) the quality of the ingredient based on a monograph contained in a default standard.

#### **2 At the end of regulation 7**

Add:

- ; (j) therapeutic goods that:
  - (i) are, or contain, a substance that is included in Schedule 3, 4 or 8 to the current Poisons Standard and is not included in Appendix H to the current Poisons Standard; and
  - (ii) are extemporaneously compounded for a particular person for therapeutic application to that person.

#### **3 Subregulation 12B(1B) (table item 4)**

Repeal the item, substitute:

4	amiloride	tablet	oral	treatment of hypokalaemia
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#### **4 Subregulation 12B(1B) (cell at table item 4A, column 5)**

Repeal the cell, substitute:

- (a) to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines; or
- (b) treatment of uterine fibroids

#### **5 Subregulation 12B(1B) (cell at table item 36, column 5)**

Repeal the cell, substitute:

- (a) prostate cancer imaging study
- (b) PET CT gallium-68 PSMA whole body uptake study

### 6 Subregulation 12B(1B) (after table item 36)

Insert:

36A	ganciclovir	gel	ophthalmic	treatment of cytomegalovirus
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### 7 Subregulation 12B(1B) (after table item 51)

Insert:

51A	metolazone	tablet	oral	treatment of fluid overload
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### 8 In the appropriate position in Part 9

Insert:

## Division 20—Application provisions relating to the Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022

### 88 Exempt goods

The amendment of item 1 of the table in Schedule 5 made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* applies in relation to therapeutic goods that are imported on or after the commencement of this regulation.

### 89 Fee for requests to vary entries in Register

- (1) The amendment of item 2A of the table in clause 3 of Schedule 9 made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 3) Regulations 2022* applies in relation to a request that is made on or after the commencement of this regulation.
- (2) If:
  - (a) on or after 1 January 2022 and before the commencement of this regulation, a person made a request of a kind covered by paragraph (c) of item 2A of the table in clause 3 of Schedule 9 (as that item was in force before that commencement); and
  - (b) on or after 1 January 2022 and before the commencement of this regulation, the person paid the fee applicable in relation to the request under paragraph (c) of that item (as that item was in force before that commencement); and

- (c) had the request been made on the day on which this regulation commences, the request would have been covered by paragraph (d) of that item as in force on that commencement;

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the request under paragraph (d) of that item if the request had been made on the day on which this regulation commences.

## 9 Schedule 5 (table item 1, column 2, paragraph (b))

Repeal the paragraph.

## 10 Schedule 5 (after table item 6)

Insert:

- 6A medicines (other than medicines that are used for gene therapy or that are medicinal cannabis products) that are:
- (a) compounded in a hospital by:
- (i) in the case of a private hospital—a hospital pharmacist who is engaged in the manufacture of therapeutic goods (other than biologicals) on the premises of the private hospital; or
  - (ii) in the case of a public hospital—a pharmacist who is employed by the public hospital and is engaged in the manufacture of therapeutic goods (other than biologicals); and
- (b) compounded in anticipation of being needed for therapeutic application to patients of the hospital; and
- (c) considered by the hospital’s drug and therapeutic committee (however called) to be appropriate for compounding in anticipation of being needed to treat a patient at the hospital

## 11 Clause 3 of Schedule 9 (table item 2A)

Omit:

- |                                                                                                                                                                                                                                 |                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| (c) a medical device                                                                                                                                                                                                            | 482                                  |
| substitute:                                                                                                                                                                                                                     |                                      |
| (c) a medical device, other than a medical device covered by paragraph (d)                                                                                                                                                      | 482                                  |
| (d) a medical device, if the following are satisfied:                                                                                                                                                                           | 190 per 10 entries (or part thereof) |
| (i) the reason for the variation is that the kind of medical device is <b>affected by the EU transition</b> (within the meaning of subregulation 9.1AA(3) of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> ); |                                      |
| (ii) the variation only relates to an update to the manufacturer’s evidence for the medical device recorded in the entry in the Register for that kind of medical device;                                                       |                                      |
| (iii) the request is to vary one or more entries in the Register and the manufacturer’s evidence to which the update relates is the same for each of the entries                                                                |                                      |

**12 Clause 3 of Schedule 9 (table item 9)**

Omit “, 41(1)(f)”.