



# **Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024**

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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 12 June 2024

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 (2024 Measures No. 2) Regulations 2024*.

## 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.	15 June 2024
2. Schedule 1	The day after this instrument is registered.	15 June 2024
3. Schedule 2	1 July 2024.	1 July 2024
4. Schedule 3	1 October 2024.	1 October 2024

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

### Part 1—Medicines Repurposing Program

#### *Therapeutic Goods Regulations 1990*

##### **1 After paragraph 35A(1)(e)**

Insert:

- (ea) the repurposing of medicines under the program known as the Medicines Repurposing Program;

##### **2 After subregulation 45(4AA)**

Insert:

*Waiver of application and evaluation fees—Medicines Repurposing Program*

- (4AB) The Secretary may waive an application fee or evaluation fee prescribed in Schedule 9 to these Regulations in relation to an application under section 23 of the Act if:
  - (a) the application is for an extension of indications of a registered medicine; and
  - (b) the Secretary is satisfied that the medicine is suitable for repurposing under the program known as the Medicines Repurposing Program.
- (4AC) The Secretary may waive a fee under subregulation (4AB) on the Secretary's own initiative or on application.

##### **3 Subregulation 48(1) (after table item 5 in the definition of *eligible person*)**

Insert:

5A	decision to refuse to waive a fee under subregulation 45(4AB) following an application referred to in subregulation 45(4AC)	the person who made the application referred to in subregulation 45(4AC)
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##### **4 Subregulation 48(1) (at the end of paragraph (g) of the definition of *initial decision*)**

Add “(other than a decision to waive a fee under subregulation 45(4AB))”.

## **Part 2—Exemption for certain prescription spectacle lenses**

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

#### **5 Part 1 of Schedule 4 (after table item 1.4)**

Insert:

- 1.4A Medical device that is prescription spectacle lenses (whether or not supplied with a mounting) if the lenses (disregarding any lens treatments) are intended, by the person under whose name the device is or is to be supplied, to be used only to provide refractive corrections

## Part 3—Classification rules for programmed or programmable medical device or software that is a medical device

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

#### 6 Subregulation 11.45(2)

After “(3)”, insert “, (4A)”.

#### 7 After subregulation 11.45(4)

Insert:

- (4A) Clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, do not apply in relation to a transitional kind of medical device before the day applicable under subregulation (4B) if:
- (a) on or after 25 February 2021, and before 1 November 2024, the person makes an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind (the *new kind*) of medical device; and
  - (b) the person has not, before 1 November 2024, made an application under the Act to have the new kind of medical device included in the Register; and
  - (c) the person has not withdrawn the conformity assessment certificate application before 1 November 2024; and
  - (d) the conformity assessment certificate application has not lapsed under section 41EG of the Act before 1 November 2024; and
  - (e) the person gives the Secretary a notice under regulation 11.46 in relation to the transitional kind of medical device; and
  - (f) the unique product identifier of the new kind of medical device contained in the conformity assessment certificate application is the unique product identifier, or one of the unique product identifiers, stated in the notice.
- (4B) For the purposes of subregulation (4A), the applicable day is the later of 1 November 2024 and the day after the earliest of the following days:
- (a) the day the person withdraws the conformity assessment certificate application;
  - (b) the day that application lapses under section 41EG of the Act;
  - (c) in the case of a decision to not issue the conformity assessment certificate and where there is no longer any possibility of a change in the outcome of that decision—the first day on which there is no longer that possibility;
  - (d) in the case of a decision to issue the conformity assessment certificate:
    - (i) if, at the end of the period of 6 months beginning on the day of the issue of the certificate, the person has not made an application under the Act to have the new kind of medical device included in the Register—the last day of that 6-month period; or
    - (ii) if, before the end of the period of 6 months beginning on the day of the issue of the certificate, the person has made an application under the Act to have the new kind of medical device included in the Register—the day applicable under subregulation (4C).



- (4C) For the purposes of subparagraph (4B)(d)(ii), the applicable day is the day after the day on whichever of the following events occurs first:
- (a) the person withdraws the application mentioned in that subparagraph;
  - (b) that application lapses under section 41FK of the Act;
  - (c) that application is finally determined.

## Part 4—Minor and technical amendments

### *Therapeutic Goods Regulations 1990*

#### 8 Subregulation 12AC(2) (note)

Omit “section 52 of the Act”, substitute “regulation 46AA”.

#### 9 Subregulation 23(1)

Omit “(1)”.

#### 10 Subregulation 23(1) (definition of *appropriately fastened and sealed*)

Repeal the definition.

#### 11 Subregulation 23(2)

Repeal the subregulation.

#### 12 Regulation 33

Repeal the regulation, substitute:

#### 33 Production of identity card

- (1) An authorised officer is not entitled to exercise any powers under this Part in relation to premises if:
  - (a) the occupier of the premises has required the authorised officer to produce the authorised officer’s identity card issued under regulation 46AA for inspection by the occupier; and
  - (b) the authorised officer fails to comply with the requirement.
- (2) For the purposes of subregulation (1), *occupier*, in relation to premises, includes a person present at the premises who is in apparent control of the premises.

#### 13 Before regulation 46A

Insert:

#### 46AA Identity cards for authorised officers

- (1) The Secretary is to ensure that each authorised officer is issued with an identity card that incorporates a recent photograph of the person.
- (2) When a person ceases to be an authorised officer, the person must, as soon as practicable after so ceasing, return the person’s identity card to the Secretary.

Penalty: 1 penalty unit.

- (3) An offence under subregulation (2) is an offence of strict liability.

#### 14 Schedule 5 (table item 1, column 2, paragraph (c))

Omit “Customs (Prohibited Imports) Regulations”, substitute “*Customs (Prohibited Imports) Regulations 1956*”.

**15 Schedule 5 (table item 11, column 2, paragraph (a))**

Omit “Customs (Prohibited Imports) Regulations”, substitute “*Customs (Prohibited Imports) Regulations 1956*”.

**16 Schedule 5A (table item 4, column 3, paragraph (c))**

Omit “Customs (Prohibited Imports) Regulations”, substitute “*Customs (Prohibited Imports) Regulations 1956*”.

## **Part 5—Transitional provisions**

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

#### **17 In the appropriate position in Part 11**

Insert:

#### **Division 11.20—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024**

##### **11.74 Definitions**

In this Division:

*amending regulations* means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024*.

##### **11.75 Exemption for certain prescription spectacle lenses**

Item 1.4A of Part 1 of Schedule 4, as inserted by Part 2 of Schedule 1 to the amending regulations, applies in relation to medical devices imported into Australia, exported from Australia, or manufactured or supplied in Australia, on or after the commencement of that item.

### ***Therapeutic Goods Regulations 1990***

#### **18 In the appropriate position in Part 9**

Insert:

#### **Division 25—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024**

##### **99 Definitions**

In this Division:

*amending regulations* means the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024*.

##### **100 Fee waivers in relation to the Medicines Repurposing Program**

Subregulation 45(4AB) of these Regulations, as inserted by Part 1 of Schedule 1 to the amending regulations, applies in relation to an application made on or after the commencement of that Schedule.

## **101 Examination, testing and analysis of goods**

The amendments of regulation 23 of these Regulations made by Part 4 of Schedule 1 to the amending regulations apply in relation to samples taken or delivered on or after the commencement of that Schedule.

## **102 Identity cards**

An identity card that had been issued to an authorised officer under regulation 33 of these Regulations before the commencement of Schedule 1 to the amending regulations, and that was in the possession of the authorised officer immediately before that commencement, is taken after that commencement to have been issued to the authorised officer under regulation 46AA of these Regulations.

## **Schedule 2—Amendments commencing 1 July 2024**

### **Part 1—Standard for sunscreen preparations**

#### *Therapeutic Goods Regulations 1990*

##### **1 Regulation 2 (definition of *Standard AS/NZS*)**

Repeal the definition.

##### **2 Schedule 4 (table item 7, column headed “Therapeutic goods”, paragraph (a))**

Omit “Standard AS/NZS 2604:2012, as in force from time to time”, substitute “Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force from time to time”.

## **Part 2—Auditing applications for inclusion of medical devices in the Register**

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

#### **3 Subregulation 5.3(1)**

Repeal the subregulation, substitute:

- (1) For the purposes of paragraph 41FH(1)(a) of the Act, and subject to this regulation, an application for any of the following kinds of medical devices to be included in the Register is prescribed:
  - (a) a Class III medical device;
  - (b) any of the following IVD medical devices:
    - (i) a Class 3 IVD medical device;
    - (ii) a Class 4 IVD medical device;
    - (iii) a Class 4 in-house IVD medical device;
    - (iv) an IVD medical device that is intended for self-testing;
    - (v) an IVD medical device that is intended for point of care testing.

#### **4 After subregulation 5.3(2AA)**

Insert:

- (2AB) Subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if:
  - (a) the kind of medical device:
    - (i) is the subject of a medical device licence issued by Health Canada under the *Medical Devices Regulations* (Canada); or
    - (ii) is the subject of an order approving an application for premarket approval from the US Food and Drug Administration under the *Federal Food, Drug, and Cosmetic Act* (United States of America); or
    - (iii) is the subject of a pre-market certification or approval issued by the Japanese Ministry of Health, Labour and Welfare, or the Japanese Pharmaceuticals and Medical Devices Agency, under *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* (Japan); or
    - (iv) is the subject of an entry in the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under the *Health Products Act 2007* (Singapore); or
    - (v) has been certified in accordance with the Australia-UK Mutual Recognition Agreement, the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement; and
  - (b) the licence, order, approval, certification or entry has not:
    - (i) been suspended, revoked or restricted (however described); or
    - (ii) otherwise ceased to be in effect.

#### **5 Subregulation 5.12(1)**

Repeal the subregulation, substitute:

- (1) This regulation applies in relation to the following kinds of medical devices:
  - (a) a Class 3 IVD medical device;

**Schedule 2** Amendments commencing 1 July 2024

**Part 2** Auditing applications for inclusion of medical devices in the Register

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- (b) a Class 4 IVD medical device;
- (c) a Class 4 in-house IVD medical device;
- (d) an IVD medical device that is intended for self-testing;
- (e) an IVD medical device that is intended for point of care testing;
- (f) a spinal fusion implantable device.

Note: For the purposes of paragraph (f), examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

**6 Regulation 11.22**

Repeal the regulation.



## **Part 3—Classification rules for medical devices containing substances of animal or microbial origin**

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

#### **7 Subclause 13.4(3) of Schedule 1 (table item 25A)**

Repeal the item, substitute:

- 25A For a medical device to which clause 5.5 of Schedule 2 applies (other than an IVD medical device), information to the effect that the device contains or incorporates any of the following:
- (a) non-viable tissues, or cells, of animal origin;
  - (b) derivatives of tissues or cells referred to in paragraph (a).

#### **8 Clause 5.5 of Schedule 2**

Repeal the clause, substitute:

#### **5.5 Medical devices containing non-viable animal tissues, cells or their derivatives**

- (1) Subject to subclause (2), this clause applies to a medical device if the device contains any of the following:
  - (a) non-viable tissues, or cells, of animal origin (other than tissues or cells from hair or wool);
  - (b) derivatives of tissues or cells covered by paragraph (a) (other than sintered hydroxyapatite or tallow derivatives).
- (2) This clause does not apply to a medical device if the device is intended by the manufacturer to come into contact with intact skin only.
- (3) A device to which this clause applies is classified as Class III.

## Part 4—Transitional provisions

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

#### 9 Regulation 11.74

Insert:

***finally determined***: an application is finally determined at the first time both the following conditions are met:

- (a) a decision has been made whether or not to grant the application;
- (b) there is no longer any possibility of a change in the outcome of the decision.

***inclusion day*** for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

***transitional medical device*** means a medical device of a kind:

- (a) that was, immediately before 1 July 2024:
  - (i) included in the Register; and
  - (ii) a kind of medical device to which clause 5.5 of Schedule 2 to these Regulations applied; and
- (b) that is, on 1 July 2024, a kind of a medical device to which clause 5.5 of Schedule 2 to these Regulations no longer applies.

#### 10 In the appropriate position in Division 11.20

Insert:

#### 11.76 Auditing of applications

- (1) The amendments of regulation 5.3 of these Regulations made by Part 2 of Schedule 2 to the amending regulations apply in relation to applications made on or after 1 July 2024.
- (2) The amendment of regulation 5.12 of these Regulations made by Part 2 of Schedule 2 to the amending regulations applies in relation to a kind of medical device included in the Register on or after 1 July 2024 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

#### 11.77 Reclassification of medical devices

*Applications and entries other than for transitional medical devices*

- (1) The amendment of clause 5.5 of Schedule 2 to these Regulations made by Part 3 of Schedule 2 to the amending regulations applies in relation to the following:
  - (a) an application for a kind of medical device to be included in the Register that is made on or after 1 July 2024;
  - (b) a kind of medical device that is included in the Register as a result of such an application.

*Applications and entries for transitional medical devices*

- (2) Subject to subregulations (3) and (4) of this regulation, the amendment of clause 5.5 of Schedule 2 to these Regulations made by Part 3 of Schedule 2 to the

amending regulations applies in relation to a transitional medical device on and after 1 July 2026.

- (3) The amendment of clause 5.5 of Schedule 2 to these Regulations made by Part 3 of Schedule 2 to the amending regulations does not apply in relation to a transitional medical device before the day applicable under subregulation (4) of this regulation, if:
  - (a) a person applies under the Act:
    - (i) on or after the inclusion day for the entry of the transitional medical device; and
    - (ii) on or after 1 July 2024; and
    - (iii) before 1 July 2026;to have a kind (the *new kind*) of medical device included in the Register; and
  - (b) the new kind of device would, but for the amendment, be the same kind of medical device as the transitional medical device.
- (4) For the purposes of subregulation (3), the day is the day after the day on which the application mentioned in paragraph (3)(a):
  - (a) is withdrawn; or
  - (b) lapses under section 41FK of the Act; or
  - (c) is finally determined.
- (5) Subregulation 5.3(1) does not apply to an application for inclusion of the new kind of device in the Register.

## ***Therapeutic Goods Regulations 1990***

### **11 In the appropriate position in Division 25 of Part 9**

Insert:

#### **103 Sunscreen preparations**

- (1) Subject to subregulations (2) and (3) of this regulation, the amendments of these Regulations made by Part 1 of Schedule 2 to the amending regulations apply to sunscreen preparations from 1 July 2024.

*Transitional testing requirements for preparations listed before 1 July 2024*

- (2) If a sunscreen preparation was listed goods immediately before 1 July 2024, paragraph (a) of the column headed “Therapeutic goods” in item 7 of the table in Schedule 4 to these Regulations applies in relation to the sunscreen preparation during the period beginning on 1 July 2024 and ending on 30 June 2029 as if the amendments had not been made.

*Transitional labelling requirements for preparations listed before 1 July 2024*

- (3) If a sunscreen preparation that is supplied as an aerosol or in a spray pump pack was listed goods immediately before 1 July 2024, paragraph (b) of the column headed “Therapeutic goods” in item 7 of the table in Schedule 4 to these Regulations applies in relation to the sunscreen preparation during the period beginning on 1 July 2024 and ending on 30 June 2025 as if the amendments had not been made.

## **Schedule 3—Amendments commencing 1 October 2024**

### ***Therapeutic Goods Regulations 1990***

#### **1 Schedule 5 (table item 6)**

Repeal the item, substitute:

- 6 medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than the following:
- (a) medicines that are used for gene therapy;
  - (b) medicines that are medicinal cannabis products;
  - (c) medicines that contain glucagon-like peptide-1 (GLP-1) receptor agonist analogues