Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

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 03 March 2022

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

OPC65757 - A

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) 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. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	5 March 2022
2. Schedule 1	31 March 2022.	31 March 2022
3. Schedule 2	The later of: (a) the day after this instrument is registered; and (b) the day on which the *Minamata Convention on Mercury (Consequential Amendments) Regulations 2021* commence. However, the provisions do not commence at all if the event mentioned in paragraph (b) does not occur.	7 March 2022 (paragraph (b) applies)
4. Schedule 3	The day after this instrument is registered.	5 March 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Note: This table relates only to the provisions of this instrument as originally made.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 following:

(a) the *Narcotic Drugs Act 1967*;

(b) 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Extemporaneously-compounded medicinal cannabis products

Narcotic Drugs Regulation 2016

1 After paragraph 4B(b)

Insert:

(ba) the supply of a cannabis drug to a person for the purposes of that person supplying an extemporaneously-compounded medicinal cannabis product (within the meaning of the *Therapeutic Goods Regulations 1990*) in accordance with the *Therapeutic Goods Act 1989*;

2 After paragraph 11(c)

Insert:

(ca) the supply is for the purposes of that person supplying an extemporaneously-compounded medicinal cannabis product (within the meaning of the *Therapeutic Goods Regulations 1990*) in accordance with the *Therapeutic Goods Act 1989*;

Therapeutic Goods Regulations 1990

3 In the appropriate position in Part 9

Insert:

Division 18—Application provisions relating to Schedule 1 to the Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

86 Extemporaneously-compounded medicinal cannabis products

The amendment of Schedule 5 to these Regulations made by Schedule 1 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* does not apply in relation to a medicinal cannabis product that is extemporaneously compounded before 28 April 2022.

4 Schedule 5 (at the end of the cell at table item 6, column 2)

Add "or that are medicinal cannabis products".

Schedule 2—Minamata Convention on Mercury

Therapeutic Goods Regulations 1990

1 Before subregulation 48(1)

Insert:

Definitions

2 Subregulation 48(1)

Insert:

eligible person, in relation to an initial decision specified in column 1 of an item of the following table, means a person specified in column 2 of the item.

Eligible persons in relation to initial decisions

Item	Column 1 Initial decision	Column 2 Eligible person
1	initial decision not covered by another item of this table	a person whose interests are affected by the initial decision
2	decision to refuse to make a therapeutic goods (priority applicant) determination	the person who applied for the determination
3	decision to revoke a therapeutic goods (priority applicant) determination	the priority applicant specified in the determination
4	decision under regulation 10JE or 10JF to refuse to approve an application for approval	the person who applied for the approval
5	decision under regulation 10JE or 10JF to revoke or vary an approval of a specified person to import or export mercury	the person specified in the approval

3 Subregulation 48(1) (at the end of the definition of *initial decision*)

Add:

Note: See also subregulation (1AA) of this regulation.

4 After subregulation 48(1)

Insert:

(1AA) Each of the following decisions of the Secretary under regulation 10JE or 10JF (about importing or exporting mercury) is an ***initial decision***:

(a) a decision to refuse to approve an application for approval;

(b) a decision to revoke or vary an approval.

Delegation

5 Before subregulation 48(2)

Insert:

Requests for reconsideration of initial decisions

6 Subregulation 48(2)

Omit "A person whose interests are affected by", substitute "An eligible person in relation to".

7 Subregulation 48(2AA)

Repeal the subregulation.

8 Before subregulation 48(3)

Insert:

Reconsideration of initial decisions

9 Before subregulation 48(6)

Insert:

Notices about right to seek reconsideration of initial decisions

10 Subregulation 48(6)

Omit "whose interests are affected by" (first occurring), substitute "who is an eligible person in relation to".

11 Subregulation 48(6)

Omit "a person whose interests are affected by the decision" (second occurring), substitute "the person".

12 Before subregulation 48(7)

Insert:

Failure to comply with subregulations (5) and (6) does not affect decisions

13 Before subregulation 48(8)

Insert:

Applications for review of reviewable decisions

14 In the appropriate position in Part 9

Insert:

Division 19—Application provisions relating to Schedule 2 to the Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022

87 Reconsideration of decisions

The amendments of regulation 48 of these Regulations made by Schedule 2 to the *Therapeutic Goods Legislation Amendment (2022 Measures No. 1) Regulations 2022* apply in relation to initial decisions made on or after the commencement of this regulation.

Schedule 3—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Subclause 13A.2(2) of Schedule 1 (table item 1, column headed "Information", paragraph (c))

Omit "; and".

2 Subclause 13A.2(2) of Schedule 1 (table item 1, column headed "Information", paragraph (d))

Repeal the paragraph.

3 Dictionary (definition of *unique device identifier*)

Repeal the definition.

Therapeutic Goods Regulations 1990

4 Subregulation 12A(1)

Omit "the 9th Schedule to the Poisons Standard, as in force from time to time", substitute "Schedule 9 or 10 to the Poisons Standard".