Therapeutic Goods Legislation Amendment (2021 Measures No. 2) 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 23 July 2021

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) 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. The whole of this instrument	The day after this instrument is registered.	28 July 2021

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Provisional determinations—COVID-19

Therapeutic Goods Regulations 1990

1 Regulation 10L

Before "For the", insert "(1)".

2 At the end of regulation 10L

Add:

(2) However, paragraphs (1)(b) and (c) do not apply if:

(a) the application under subsection 22C(1) of the Act is made on or after the commencement of this subregulation; and

(b) an indication of the medicine is the treatment or prevention of the disease known as coronavirus disease (COVID-19).

Part 2—Nicotine vaping products

Therapeutic Goods (Medical Devices) Regulations 2002

3 At the end of regulation 7.1

Add:

Limited exemptions

(4) For a kind of medical device that is exempt under paragraph (a) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the importation.

(5) For a kind of medical device that is exempt under paragraph (b) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the manufacture.

(6) For a kind of medical device that is exempt under paragraph (c) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the supply by the intermediate supplier.

(7) For a kind of medical device that is exempt under paragraph (d) of item 1.6 of the table in Part 1 of Schedule 4, the exemption is subject to the condition that the exemption only has effect in relation to the supply covered by that paragraph.

4 Part 1 of Schedule 4 (at the end of the table)

Add:

1.5	Medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in the *Therapeutic Goods Regulations 1990* and that is imported into Australia or manufactured or supplied in Australia.
1.6	The following: (a) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is imported into Australia; and (iii) the sponsor reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (b) a medical device that is a system or procedure pack where: (i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and (ii) the system or procedure pack is manufactured in Australia; and (iii) the manufacturer reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act;

(c) a medical device that is a system or procedure pack where:
(i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and
(ii) the system or procedure pack is supplied in Australia by a person (the ***intermediate supplier***) to a person who is not the ultimate consumer of the system or procedure pack; and
(iii) the intermediate supplier reasonably expects that the system or procedure pack will be supplied to its ultimate consumer in circumstances where the nicotine vaping product will be the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act;

(d) a medical device that is a system or procedure pack where:
(i) the system or procedure pack consists of a nicotine vaping product (within the meaning of the *Therapeutic Goods Regulations 1990*) and a medical device that is a vaping device referred to in paragraph (c) of the definition of ***nicotine vaping product*** in those regulations; and
(ii) the system or procedure pack is supplied in Australia to its ultimate consumer; and
(iii) at the time of that supply, the nicotine vaping product is the subject of an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act.

5 Part 2 of Schedule 4 (table item 2.11A, column headed "Kinds of medical devices")

Omit "and administration", substitute ", and administration by inhalation,".

Therapeutic Goods Regulations 1990

6 Regulation 2

Insert:

nicotine vaping product means a medicine that:
(a) contains nicotine in solution; and
(b) is a finished product; and
(c) is intended to be vaporised, and administered by inhalation, using a vaping device.

7 At the end of regulation 12

Add:

Limited exemptions

(5) For therapeutic goods exempt under paragraph (a) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the importation.

(6) For therapeutic goods exempt under paragraph (b) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the manufacture.

(7) For therapeutic goods exempt under paragraph (c) of item 5 of the table in Schedule 5, the exemption is subject to the condition that the exemption only has effect in relation to the supply by the intermediate supplier.

8 Schedule 5 (after table item 4)

Insert:

5	The following goods: (a) a nicotine vaping product where: (i) that product is imported; and (ii) the sponsor reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (b) a nicotine vaping product where: (i) that product is manufactured by the holder of a licence; and (ii) the manufacturer reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act; (c) a nicotine vaping product where: (i) that product is supplied in Australia by a person (the ***intermediate supplier***) to a person who is not the ultimate consumer of the product; and (ii) the intermediate supplier reasonably expects that product to be supplied to the ultimate consumer of the product in accordance with an approval under subsection 19(1) of the Act or an authority under subsection 19(5) of the Act.	

Part 3—Conformity assessment

Therapeutic Goods (Medical Devices) Regulations 2002

9 Regulation 4.1

Repeal the regulation.

10 Subregulation 5.3(1)

Omit "subregulation (2) or (2A)", substitute "this regulation".

11 After subparagraph 5.3(1)(j)(viii)

Insert:

(viiia) a Class 4 IVD medical device;

12 After subregulation 5.3(2)

Insert:

(2AA) Subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if:

(a) an overseas regulator conformity assessment document has been issued, in respect of the kind of medical device, by a notified body (within the meaning of the *Therapeutic Goods (Overseas Regulators) Determination 2018*) in accordance with:

(i) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, as in force from time to time; or

(ii) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, as in force from time to time; and

(b) the overseas regulator conformity assessment document has not been suspended or revoked.

Part 4—Other amendments

Therapeutic Goods Regulations 1990

13 Schedule 5 (table item 9, column 2)

Omit "medicines or biologicals that are starting materials used", substitute "Starting materials that are ingredients or components for use".

Part 5—Application provisions

Therapeutic Goods (Medical Devices) Regulations 2002

14 In the appropriate position in Part 11

Insert:

Division 11.12—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

11.58 Application provisions

Nicotine vaping products

(1) Item 1.5 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to the following:

(a) a medical device imported or manufactured on or after the commencement of that item;

(b) a medical device supplied on or after the commencement of that item, where that device was imported or manufactured on or after that commencement.

System or procedure packs

(2) Paragraph (a) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack imported on or after the commencement of that item.

(3) Paragraph (b) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack manufactured on or after the commencement of that item.

(4) Paragraph (c) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack supplied on or after the commencement of that item, where that system or procedure pack was imported or manufactured on or after that commencement.

(5) Paragraph (d) of item 1.6 of the table in Part 1 of Schedule 4, as added by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a system or procedure pack supplied on or after the commencement of that item, where that system or procedure pack was imported or manufactured on or after that commencement.

Conformity assessment

(6) The amendments made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* apply in relation to an application for a kind of medical device to be included in the Register that is made on or after the commencement of that Part.

Therapeutic Goods Regulations 1990

15 In the appropriate position in Part 9

Insert:

Division 14—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

78 Exempt goods

(1) Paragraph (a) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product imported on or after the commencement of that item.

(2) Paragraph (b) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product manufactured on or after the commencement of that item.

(3) Paragraph (c) of item 5 of the table in Schedule 5, as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, applies in relation to a nicotine vaping product supplied on or after the commencement of that item, where that product was imported or manufactured on or after that commencement.