



Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020

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 17 December 2020

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020*.

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.	19 December 2020

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 Part 2 of Schedule 4 (at the end of the table)

Add:

- 2.11A Medical device that:
- (a) is intended, by the person under whose name the device is or is to be supplied, to be used for the vapourisation and administration of a medicine that is registered goods:
 - (i) whose only active ingredient is nicotine; and
 - (ii) whose only indication accepted in relation to inclusion of the goods in the Register relates to use, by means of the device, for smoking cessation; or
 - (b) is a system or procedure pack consisting of a device described in paragraph (a) and a medicine described in paragraph (a)
- (a) The device must comply with the essential principles.
 - (b) The manufacturer of the device must apply the appropriate conformity assessment procedures at all times.
 - (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request:
 - (i) whether the device complies with the essential principles;
 - (ii) whether the conformity assessment procedures have been applied to the device;
 - (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.
 - (d) The manufacturer of the device must, at all times, have available:
 - (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or
 - (ii) information relating to changes to the device and quality management system.
 - (e) The manufacturer of the device must allow an authorised person to do any of the following:
 - (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device;
 - (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device;
 - (iii) make any still or moving image or any recording of those premises or anything on those premises.
 - (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents.
 - (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.

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- (h) The manufacturer or sponsor of the device must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods:
- (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information.
- (i) The person under whose name the device is or is to be supplied must keep records relating to the importation or supply of the device by or on behalf of the person.
- (j) The person under whose name the device is or is to be supplied must, on request by the Secretary, provide to the Secretary those records within 20 working days of receiving the request or a longer period agreed to by the Secretary.