



Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) 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 25 June 2020

David Hurley
Governor-General

By His Excellency's Command

Jason Wood
Assistant Minister for Customs, Community Safety and Multicultural Affairs
Parliamentary Secretary to the Minister for Home Affairs

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1 Name

This instrument is the *Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) 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	1 July 2020.	1 July 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Note: This table relates only to the provisions of this instrument as originally made.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 *Customs Act 1901*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Customs (Prohibited Imports) Regulations 1956

1 After regulation 4DA

Insert:

4DB Importation of personal nicotine vaporisers

Importation of personal nicotine vaporisers by post is prohibited absolutely

- (1) The importation of a personal nicotine vaporiser into Australia by post is prohibited absolutely.

Importation of personal nicotine vaporisers by any other means without permission is prohibited

- (2) The importation of a personal nicotine vaporiser into Australia by any other means is prohibited unless:
 - (a) a permission to import the personal nicotine vaporiser has been granted in writing by the Secretary or an authorised person; and
 - (b) the permission is produced to the Collector.

Exemption from prohibition

- (3) Despite subregulation (2), a personal nicotine vaporiser may be imported into Australia by a person who is a passenger on board a ship or aircraft if:
 - (a) vaporiser nicotine is required for the medical treatment of the person or of another passenger under the care of the person; and
 - (b) the vaporiser nicotine is for use in the personal nicotine vaporiser; and
 - (c) the use of the vaporiser nicotine in the personal nicotine vaporiser was prescribed by a medical practitioner for the purposes of that treatment; and
 - (d) the vaporiser nicotine in the personal nicotine vaporiser was supplied to the person in accordance with the prescription of the medical practitioner referred to in paragraph (c).

Application for permission

- (4) A medical practitioner or sponsor may apply, in writing, for a permission under subregulation (2) to import a personal nicotine vaporiser. The application must:
 - (a) be lodged with the Secretary or an authorised person; and
 - (b) if the applicant is a medical practitioner—include a copy of an approval granted to the applicant under subsection 19(1) of the *Therapeutic Goods Act 1989* that allows the applicant to import into Australia vaporiser nicotine for use:
 - (i) in the personal nicotine vaporiser; and
 - (ii) in the treatment of a person named in the application; and
 - (c) if the applicant is a medical practitioner and paragraph (b) does not apply—include a copy of an authorisation granted to the applicant under subsection 19(5) of that Act that allows the applicant to supply vaporiser nicotine for use:

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- (i) in the personal nicotine vaporiser; and
 - (ii) in the treatment of a class of persons specified in the authority, being a class that covers a person named in the application; and
 - (d) if the applicant is a sponsor—state that the application is being made on the basis that:
 - (i) the personal nicotine vaporiser is a therapeutic good mentioned in column 2 of item 1 in Schedule 5A to the *Therapeutic Goods Regulations 1990*; and
 - (ii) the conditions mentioned in column 3 of that item will be complied with in respect of the personal nicotine vaporiser.

The applicant must give to the Secretary or authorised person any information that the Secretary or authorised person reasonably requires for the purpose of making a decision on the application.

Dealing with application for permission

- (5) In considering whether to grant a permission, the Secretary or authorised person may consider any relevant matter.
- (6) However, the Secretary or authorised person must not grant a permission unless the applicant gives all the information the Secretary or authorised person requires under subregulation (4).
- (7) If the Secretary or authorised person decides to grant a permission to import a personal nicotine vaporiser, the Secretary or authorised person must give written notice of the decision to the applicant.
- (8) A permission granted under subregulation (7) may:
 - (a) set out conditions or requirements with respect to the possession, safe custody, transportation, use or disposal of the personal nicotine vaporiser, to ensure that the personal nicotine vaporiser imported is only used for the purpose for which the permission is granted; and
 - (b) in respect of any such condition or requirement, specify the time, whether before or after the personal nicotine vaporiser is imported, at which the condition or requirement is to be complied with by the holder of the permission.
- (9) If a permission is granted by the Secretary or authorised person, the permission must set out:
 - (a) both:
 - (i) the name and address of the holder of the permission; and
 - (ii) the name of the supplier and the supplier's physical address in the country from which the personal nicotine vaporiser was exported; and
 - (b) the conditions or requirements to which the permission is subject (if any).

Note: Failure to comply with a condition is an offence, see subsection 50(4) of the Act.

Revocation of permission

- (10) The Secretary or authorised person may revoke a permission if the holder of the permission fails to comply with a condition or requirement of the permission.

Notice of decision to refuse or revoke permission

- (11) If the Secretary or authorised person decides:

- (a) not to grant a permission; or
- (b) to revoke a permission;

the Secretary or authorised person must give the applicant or holder of the permission written notice of the decision as soon as practicable after making it.

- (12) Application may be made to the Administrative Appeals Tribunal for review of a decision of the Secretary or of an authorised person:
- (a) not to grant a permission; or
 - (b) to grant a permission subject to a condition or requirement; or
 - (c) to revoke a permission.
- (13) A notice under subregulation (7) or (11) must include:
- (a) a statement to the effect that application may be made to the Tribunal under the *Administrative Appeals Tribunal Act 1975* for review of the decision to which the notice relates; and
 - (b) except where subsection 28(4) of that Act applies—a statement to the effect that a person who is entitled to apply to the Tribunal for review of the decision may, under section 28 of that Act, request a statement that includes the reasons for the decision.

Sunset of this regulation

- (14) This regulation is repealed on 1 July 2021.

Definitions

- (15) In this regulation:

authorised person means a person who is authorised in an instrument under subregulation (16).

Health Department means the Department administered by the Minister administering the *Therapeutic Goods Act 1989*.

medical practitioner:

- (a) for the purposes of subregulation (3)—means a person authorised to practice as a medical practitioner under a law of a State, a Territory or another country; and
- (b) for the purposes of subregulation (4)—means a person authorised to practice as a medical practitioner under a law of a State or Territory.

personal nicotine vaporiser means a device that:

- (a) contains a cartridge, capsule or other container that contains vaporiser nicotine; and
- (b) is intended to produce a vapour or aerosol that is delivered into a person's body when the person inhales through the device.

Note: Examples of devices that would be personal nicotine vaporisers are e-cigarettes, e-cigars, e-hookah pens, e-pens, e-pipes and vape pens.

Secretary means the Secretary of the Health Department.

sponsor has the same meaning as in the *Therapeutic Goods Act 1989*.

vaporiser nicotine means:

- (a) nicotine in a solution; or

(b) nicotine in a salt or base form.

Note: Vaporiser nicotine may also be described as nicotine vape liquid, nicotine e-liquid or simply e-liquid.

Authorised person instrument

- (16) The Secretary may, in writing, authorise an APS employee in the Health Department for the purposes of the definition of **authorised person** in subregulation (15).

4DC Importation of vaporiser nicotine

Importation of vaporiser nicotine by post is prohibited absolutely

- (1) The importation of vaporiser nicotine into Australia by post is prohibited absolutely.

Importation of vaporiser nicotine by any other means without permission is prohibited

- (2) The importation of vaporiser nicotine into Australia by any other means is prohibited unless:
- (a) a permission to import vaporiser nicotine has been granted in writing by the Secretary or an authorised person; and
 - (b) the permission is produced to the Collector.

Exemption from prohibition

- (3) Despite subregulation (2), vaporiser nicotine may be imported into Australia by a person who is a passenger on board a ship or aircraft if:
- (a) the vaporiser nicotine is for use in a personal nicotine vaporiser; and
 - (b) the vaporiser nicotine is required for the medical treatment of the person or of another passenger under the care of the person; and
 - (c) the use of the vaporiser nicotine was prescribed by a medical practitioner for the purposes of that treatment; and
 - (d) the vaporiser nicotine was supplied to the person in accordance with the prescription for the use of the personal nicotine vaporiser, as referred to in paragraph (c); and
 - (e) the quantity of the vaporiser nicotine imported is not more than 3 months' supply at the maximum dose recommended by the manufacturer.

Application for permission

- (4) A person may apply, in writing, for a permission under subregulation (2) to import vaporiser nicotine. The application must:
- (a) be lodged with the Secretary or an authorised person; and
 - (b) if the applicant is a medical practitioner—include a copy of an approval granted to the applicant under subsection 19(1) of the *Therapeutic Goods Act 1989* that allows the applicant to import into Australia vaporiser nicotine for use in the treatment of a person named in the application; and
 - (c) if the applicant is a medical practitioner and paragraph (b) does not apply—include a copy of an authorisation granted to the applicant under subsection 19(5) of that Act that allows the applicant to supply vaporiser

- nicotine for use in the treatment of a class of persons specified in the authority, being a class that covers a person named in the application; and
- (d) if the applicant is a sponsor—state that the application is being made on the basis that:
- (i) the vaporiser nicotine is a therapeutic good mentioned in column 2 of item 1 in Schedule 5A to the *Therapeutic Goods Regulations 1990*; and
 - (ii) the conditions mentioned in column 3 of that item will be complied with in respect of the vaporiser nicotine; and
- (e) if the applicant is a person and paragraphs (b), (c) and (d) do not apply—state that the application is being made on the basis that:
- (i) the vaporiser nicotine is required for use by the applicant or another person solely for scientific purposes; or
 - (ii) the vaporiser nicotine is required solely for industrial use by the applicant or another person.

The applicant must give to the Secretary or authorised person any information that the Secretary or authorised person reasonably requires for the purpose of making a decision on the application.

Dealing with application for permission

- (5) In considering whether to grant a permission, the Secretary or authorised person may consider any relevant matter.
- (6) However, the Secretary or authorised person must not grant a permission unless the applicant gives all the information the Secretary or authorised person requires under subregulation (4).
- (7) If the Secretary or authorised person decides to grant a permission to import vaporiser nicotine, the Secretary or authorised person must give written notice of the decision to the applicant.
- (8) A permission granted under subregulation (7) may:
- (a) set out conditions or requirements with respect to the possession, safe custody, transportation, use or disposal of the vaporiser nicotine, or the personal nicotine vaporiser in which the vaporiser nicotine is to be used, to ensure that the vaporiser nicotine imported is only used for the purpose for which the permission is granted; and
 - (b) in respect of any such condition or requirement, specify the time, whether before or after the vaporiser nicotine is imported, at which the condition or requirement is to be complied with by the holder of the permission.
- (9) If a permission is granted by the Secretary or authorised person, the permission must set out:
- (a) both:
 - (i) the name and address of the holder of the permission; and
 - (ii) the name of the supplier and the supplier's physical address in the country from which the vaporiser nicotine was exported; and
 - (b) the conditions or requirements to which the permission is subject (if any).

Note: Failure to comply with a condition is an offence, see subsection 50(4) of the Act.

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