

## EXPLANATORY STATEMENT

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

*Customs Act 1901*

*Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations  
2020*

The purpose of the *Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020* (the Regulations) is to amend the *Customs (Prohibited Imports) Regulations 1956* (the PI Regulations) to implement a temporary prohibition on the importation of personal vaporisers such as e-cigarettes that contain nicotine in a solution, or in a base or salt form (either referred to as ‘vaporiser nicotine’) and vaporiser nicotine, for a period of 12 months commencing on 1 July 2020 .

The *Customs Act 1901* (the Customs Act) concerns customs related functions and is the legislative authority that sets out the customs requirements for the importation and exportation of goods to and from Australia.

Subsection 270(1) of the Customs Act provides, in part, that the Governor-General may make regulations not inconsistent with the Act prescribing all matters, which by the Act are required or permitted to be prescribed or as may be necessary or convenient to be prescribed for giving effect to the Act.

Section 50 of the Customs Act provides, in part, that the Governor-General may, by regulation, prohibit the importation of goods into Australia and that the power may be exercised by prohibiting the importation of goods absolutely or by prohibiting the importation of goods unless specified conditions or restrictions are complied with.

The prohibition assists in reducing the risk to public health through addiction to nicotine and nicotine poisoning.

### *Risk of addiction*

There is currently insufficient evidence that nicotine-containing e-cigarettes are an effective cessation tool for current smokers. There are, however, significant risks associated with exposure to nicotine. It is highly addictive and there is a risk of nicotine dependence when used with e-cigarettes. There is strong evidence that nicotine-containing e-cigarettes, particularly those with added flavours, provide a gateway for adolescents and young adults to dependence on nicotine-containing e-cigarettes or to cigarette smoking. For example, in the USA, there was a 78 % increase in the numbers of high school children who are using e-cigarettes over the most recent 12-month period surveyed. This indicates that, without action, Australian youth may also be at risk.

### *Risk of nicotine poisoning*

Nicotine is also highly toxic and poses significant health risks including adverse cardiovascular, respiratory and reproductive effects and negative effects on foetal and adolescent development. Ingestion of just 1-2 mL of nicotine in e-cigarette fluid refills, many of which have fruit or candy flavours and thus are attractive to children, can kill a toddler.

There has been a significant increase in poisons centres calls following e-cigarette liquid ingestion by toddlers and children (200 in 2013-16), and several toddler deaths globally including one in Melbourne in June 2018.

Currently, the commercial sale of e-cigarettes containing vaporiser nicotine is prohibited in all States and Territories, and their possession is prohibited in four of the States and Territories. This new regulation further strengthens Australia's precautionary approach to e-cigarettes by prohibiting the importation of nicotine containing e-cigarettes or vaporisers and nicotine for use in relevant devices unless exempt in specific circumstances. E-cigarette users, who in conjunction with their doctor believe that use of nicotine e-cigarettes can help them stop smoking can, under prescription, still access the products. Access on a doctor's prescription means that their health can be appropriately monitored.

The prohibition allows time for public consultation and advice from the ministerial expert Advisory Committee on Chemicals Scheduling and the Advisory Committee on Medicines Scheduling on a proposed amendment to the Poisons Standard, a legislative instrument made under the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act). The proposed Poison Standard amendment would have the effect that nicotine products, including nicotine-containing e-cigarettes would require a valid prescription (except for tobacco cigarettes or Therapeutic Goods Administration-approved smoking cessation products)

Details of the Regulations are set out in [Attachment A](#).

A Statement of Compatibility with Human Rights has been prepared in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*, and is at [Attachment B](#).

The amendments were discussed with the States and Territories which, consistently with their prohibition on domestic sale of e-cigarettes including vaporiser nicotine, support the prohibition on importation unless exempt in the specified circumstances. Reflecting the prohibition on domestic commercial supply, the prohibition on importation is not expected to affect Australian suppliers of devices, accessories and non-nicotine containing e-cigarettes. Further, persons are still able to access nicotine-containing e-cigarettes and nicotine-containing e-cigarette fluids and salts provided they have a relevant authority of a medical practitioner for smoking cessation purposes. In addition, the proposed clarification of the appropriate schedule in the Poisons Standard of nicotine is subject to its own rigorous consultation process under the Therapeutic Goods Act expected to conclude towards the end of 2020.

The Office of Best Practice Regulation has advised that a Regulation Impact Statement is not required (OBPR 26377).

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The whole of the Regulations commence on 1 July 2020.

*OPC64610 - C*

**Details of the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020**

**Section 1 – Name of Regulation**

This section provides that the title of the Regulations is the *Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020* (the Regulations).

**Section 2 – Commencement**

This section sets out, in a table, the date on which each of the provisions contained in the Regulations commences.

Table item 1 provides for the whole of the instrument to commence on 1 July 2020.

**Section 3 – Authority**

This section sets out the authority under which the Regulations are to be made, which is the *Customs Act 1901* (the Customs Act).

**Section 4 – Schedules**

This section is the formal enabling provision for the Schedules to the Regulations, and provides that each instrument that is specified in a Schedule to the Regulations are amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to this instrument has effect according to its terms.

The instrument to be amended is the *Customs (Prohibited Imports) Regulations 1956* (the PI Regulations).

**Schedule 1 – Amendments**

*Customs (Prohibited Imports) Regulations 1956*

**Item 1 – After regulation 4DA**

This item inserts two new regulations into the PI Regulations, after current regulation 4DA. The two new regulations are:

- regulation 4DB Importation of personal nicotine vaporisers; and
- regulation 4DC Importation of vaporiser nicotine.

**Regulation 4DB Importation of personal nicotine vaporisers**

Regulation 4DB implements a prohibition on the importation of personal nicotine vaporisers, as described below:

*Importation of personal nicotine vaporisers by post is prohibited absolutely*

**New subregulation 4DB(1)**

New subregulation 4DB(1) provides that the importation of a personal nicotine vaporiser by post is prohibited absolutely. It is not possible to apply for permission to import a personal nicotine vaporiser through the post and any permission granted under regulation 4DB(2) does not apply in relation to importations by post. However, if permission under subregulation 4DB(2) has been granted, cargo and courier services can be used, or a commercial organisation that handles prescription e-cigarettes can also import the products through these routes.

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

#### New subregulation 4DB(2)

New subregulation 4DB(2) provides that the importation of personal nicotine vaporisers by any other means, that is, by air or sea, is prohibited unless permission has been granted by the Secretary or an authorised person, and that permission is produced to the Collector. However, the possibility of applying for and being granted permission is not available for importation by post, which is prohibited absolutely, as noted above.

The terms ‘personal nicotine vaporiser’ and ‘Secretary’ are defined in new subregulation 4DB(15), as follows:

‘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.

A note to that definition confirms that examples of such devices are personal nicotine vaporisers that are e-cigarettes, e-cigars, e-hookah pens, e-pens and vape pens.

‘vaporiser nicotine’ is defined as nicotine in a solution, or in a base or salt form. A note to that definition confirms that vaporiser nicotine may also be described as nicotine vape liquid, nicotine e-liquid or simply e-liquid.

‘Secretary’ means the Secretary to the Health Department, which is subsequently defined as the Department administered by the Minister administering the *Therapeutic Goods Act 1989* (Therapeutic Goods Act).

Under new subregulation 4DB(16), described below, the Secretary may, in writing, authorise an APS employee in the Health Department to be an ‘authorised person’ for the purpose of the exercising the powers or performing the functions of the Secretary under regulation 4DB.

The effect of subregulation 4DB(2) is that a person may not import a personal nicotine vaporiser unless they have already sought and been granted permission for the importation from the Secretary, and have provided the permission to an officer in the Australian Border Force (the ABF). Permission cannot be granted after the personal nicotine vaporiser arrives in Australia.

*Exemption from prohibition*

#### New subregulation 4DB(3)

New subregulation 4DB(3) provides an exemption from the prohibition in subregulation 4DB(2) such that a person who is a passenger on board a ship or aircraft may import a personal nicotine vaporiser without having to seek permission if the following requirements are met:

- (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).

The term ‘medical practitioner’ is defined in subregulation 4DB(15), for the purposes of this subregulation, as a person authorised to practice as a medical practitioner under a law of a State, a Territory or another country.

The effect of new subregulation 4DB(3) is to enable a passenger on an aircraft who has been prescribed a personal nicotine vaporiser for medical treatment by a medical practitioner in, for example, France, to bring a personal nicotine vaporiser with them to Australia without having to seek permission under subregulation 4DB(2).

#### *Application for permission*

#### New subregulation 4DB(4)

New subregulation 4DB(4) sets out who may apply for permission to import a personal nicotine vaporiser and the requirements to be met by an applicant.

An applicant can be either a medical practitioner or a sponsor.

For the purpose of subregulation 4DB(4), a ‘medical practitioner’ means a person authorised to practice as a medical practitioner under a law of a State or Territory.

The term ‘sponsor’ is defined in subregulation 4DB(15) as having the same meaning as in the Therapeutic Goods Act. Under subsection 3(1) of the Therapeutic Goods Act, the term ‘sponsor’ means:

- (a) a person who exports, or arranges the exportation of, the goods from Australia; or
  - (b) a person who imports, or arranges the importation of, the goods into Australia; or
  - (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);
- but does not include a person who:
- (d) exports, imports or manufactures the goods; or
  - (e) arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

An application made by a medical practitioner or sponsor under subregulation 4DB(4) must be:

- (a) lodged with the Secretary or an authorised person; and
- (b) if the applicant is a health practitioner, include a copy of an approval granted to the applicant under subsection 19(1) of the Therapeutic Goods Act that allows the applicant to import vapouriser nicotine for use:
  - (i) in a personal nicotine vapouriser; and
  - (ii) in the treatment of a person named in the application.

Under subsection 19(1) of the Therapeutic Goods Act, the Secretary to the Department administered by the Minister administering the Therapeutic Goods Act (currently the Department of Health) may grant an approval for the importation of specified goods that, relevantly, are not entered on the Australian Register of Therapeutic Goods or the subject of an exemption under the Therapeutic Goods Act, for use either in the treatment of another person or solely for experimental purposes in humans.

The effect of paragraph 4DB(4)(b) is to enable a medical practitioner to apply for permission to import a personal nicotine vapouriser if the medical practitioner holds an approval granted to the medical practitioner under subsection 19(1) of the Therapeutic Goods Act in which approval is given for the treatment of a person at the time of making the application. The scheme under subsection 19(1) of the Therapeutic Goods Act is more commonly known as the Special Access Scheme B administered by the Therapeutic Goods Administration (a part of the Department of Health).

(c) if the applicant is a medical practitioner to whom approval granted under subsection 19(1) of the Therapeutic Goods Act does not apply, include a copy of an authorisation granted to medical practitioner under subsection 19(5) of the Therapeutic Goods Act that allows the medical practitioner to supply vapouriser nicotine for use:

- (i) in a personal nicotine vapouriser; and
- (ii) in the treatment of a class of persons specified in the authorisation that includes a person named in the application.

Under subsection 19(5) of Therapeutic Goods Act the Secretary may authorise a specified medical practitioner to supply specified therapeutic goods for use in the treatment of humans, or a specified class of such goods to recipients named in the authority. The scheme under subsection 19(5) of the Therapeutic Goods Act is more commonly known as the Authorised Prescriber scheme administered by the Therapeutic Goods Administration.

The effect of paragraph 4DB(4)(c) is to enable medical practitioners to apply for permission to import a personal nicotine vapouriser if the medical practitioner is appropriately authorised under subsection 19(5) at the time of making the application.

The combined effect of paragraph 4DB(4)(b) and (c) is to only allow medical practitioners who hold either an approval under subsection 19(1) or an authorisation under subsection 19(5) of the Therapeutic Goods Act to apply for permission to import personal nicotine

vaporisers. As a practical matter, it is anticipated that a pharmacist may, acting as the agent of a relevant medical practitioner given an approval or authorisation by the Therapeutic Goods Administration, make the application for the relevant permission. The applicant would remain the medical practitioner.

(d) if the applicant is a sponsor, the application must 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* (the Therapeutic Goods Regulations); and

(ii) the conditions mentioned in column 3 of that item will be complied with in respect of the personal nicotine vaporiser.

The conditions in column 3 of item 1 in Schedule 5A to the Therapeutic Goods Regulations are as follows:

a) the supply of the goods must be in accordance with the relevant notification, approval, authorisation or prescription; and

(b) the goods must be kept in a warehouse or a properly secured area under the control of the sponsor; and

(d) the sponsor must:

(i) keep records relating to the source and supply of the goods; and

(iii) if requested by the Secretary, give the records to the Secretary.

The effect of paragraph 4DB(4)(d) is that only an importer, the sponsor under the Therapeutic Goods Act, who meets the 'lock and key' and record keeping conditions under the Therapeutic Goods Regulations may apply for permission to import a personal nicotine vaporiser.

The applicant will be required to provide any information reasonably required by the Secretary or authorised person to decide the application.

#### *Dealing with application for permission*

##### New subregulation 4DB(5)

New subregulation 4DB(5) provides that the Secretary or a person authorised may consider any matter that is relevant in determining whether to grant permission to import a personal nicotine vaporiser to an importer.

The effect of this provision is to allow the Secretary or authorised person to consider factors such as, for example, an importer's history of compliance with other import permissions or compliance with State or Territory laws for vaporiser nicotine.

##### New subregulation 4DB(6)

Under new subregulation 4DB(6) the Secretary or an authorised person must not permit the importation of a personal nicotine vaporiser where an applicant fails to provide all information reasonably required under subregulation (4).

##### New subregulation 4DB(7)

New subregulation 4DB(7) provides that if the Secretary or an authorised person decides to grant a permission to import a personal nicotine vaporiser, written notice of the decision must be given to the applicant.

#### New subregulation 4DB(8)

New paragraph 4DB(8)(a) sets out the types of conditions or requirements that may apply to the permission granted under subregulation 4DB(7). These may be in respect of 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.

Paragraph 4DB(8)(b) provides that, for any conditions or requirements that have been set out in a permission granted, the Secretary or authorised person may also specify the time at which a condition or requirement must be complied with by the importer to whom the permission has been granted, that is, to a medical practitioner or sponsor.

#### New subregulation 4DB(9)

Under new subregulation 4DB(9) where a permission is granted by the Secretary or authorised person, it has to include both the name and address of the holder of the permission, and the supplier's name and physical address in the country from which the personal nicotine vaporiser was exported. It also has to set out any conditions or requirements to which the permission is subject.

Inclusion of these details enables efficient administration and monitoring of compliance with the permissions granted.

The note to subregulation 4DB(9) informs a holder of a permission that failure to comply with a condition or requirement of the permission is an offence under subsection 50(4) of the Customs Act. Subsection 50(4) provides for an offence as follows:

A person commits an offence if:

- (a) a licence or permission has been granted, on or after 16 October 1963, under the regulations; and
- (b) the licence or permission relates to goods that are not narcotic goods; and
- (c) the licence or permission is subject to a condition or requirement to be complied with by the person; and
- (d) the person engages in conduct; and
- (e) the person's conduct contravenes the condition or requirement.

The penalty for this offence is 100 penalty units. A penalty point will be \$222 for offences committed on or after 1 July 2020.

#### *Revocation of permission*

#### New subregulation 4DB(10)

New subregulation 4DB(10) provides that the Secretary or authorised person may revoke a permission if the holder fails to comply with a condition or requirement that applies to it.

Revocation of the permission is in addition to possible prosecution for the offence under subsection 50(4) of the Customs Act described above.

#### *Notice of decision to refuse or revoke permission*

#### New subregulations 4DB(11), (12) and (13 )

Under new subregulation 4DB(11), if the Secretary or authorised person decides to either not grant or to revoke a permission to import a personal nicotine vaporiser, they have to give written notice of the decision to the applicant (in the case of a decision not to grant a permission) or the holder (in the case of a permission already granted) as soon as practicable.

New subregulation 4DB(12) authorises an application to be made to the Administrative Appeals Tribunal for review of a decision of the Secretary or authorised person not to grant a permission, or to grant a permission subject to a condition or requirement, or to revoke a permission.

New subregulation 4DB(13) provides that a notice issued under new subregulation 4DB(7) or 4DB(11) must inform the applicant or permission holder that they may apply to the Administrative Appeals Tribunal for review of the decision. In addition, the notice must also confirm that an applicant or permission holder who is entitled to review of the decision may request a statement that includes the reasons for the decision. However, an applicant or permission holder may not request such a statement where subsection 28(4) of the *Administrative Appeals Tribunal Act 1975* (the AAT Act) applies.

Subsection 28(4) of the AAT Act provides:

#### *When applicant not entitled to request statement of reasons*

28(4) The applicant is not entitled to make a request under subsection (1) if:

- (a) the decision sets out the findings on material questions of fact, refers to the evidence or other material on which those findings were based and gives the reasons for the decision, and a document setting out the terms of the decision has been given to him or her; or
- (b) a statement in writing setting out the findings on material questions of fact, referring to the evidence or other material on which those findings were based and giving the reasons for the decision has already been given to him or her.

The effect of these provisions is that where an application for a permission to import a personal nicotine vaporiser is not granted or a permission to import one is revoked, the Secretary or authorised only has to provide reasons for the decision once. This will be either in the decision not to grant or to revoke, or in a statement requested by the applicant or permission holder.

#### *Sunset of this regulation*

#### New subregulation 4DB(14)

New subregulation 4DB(14) provides that new regulation 4DB will be repealed on 1 July 2021. The effect of this is that each provision in the new regulation ceases to have effect on and after that date so that the prohibition on the importation of a personal nicotine vaporiser under this regulation no longer exists, along with the associated provisions relating to the exemption from the prohibition or permission.

## *Definitions*

### New subregulation 4DB(15)

New subregulation 4DB(15) provides definitions for eight terms used in regulation 4DB, as follows:

- ‘authorised person’ means a person who is authorised in an instrument under subregulation 4DB(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.

A note to this definition provides that examples of devices that are 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 nicotine in a solution, or in a base or salt form.

A note to this definition provides that vaporiser nicotine may also be described as nicotine vape liquid, nicotine e-liquid or simply e-liquid.

### *Authorised person instrument*

### New subregulation 4DB(16)

New subregulation 4DB(16) provides that the Secretary may, in writing, authorise an APS employee in the Department of Health to be an ‘authorised person’ for the purpose of exercising the powers or performing the functions of an authorised person set out in regulation 4DB.

It is appropriate for the Secretary to be able to authorise an APS employee in the Department of Health as an authorised person due to their experience in currently deciding applications for drugs under Regulation 5 of the PI Regulations and due to the large volume of permissions that may need to be dealt with under the Regulations. Decisions in relation to granting, revoking or refusing a permission are anticipated to need to be made on a regular basis. Delegation to an APS level employee is necessary to ensure applications can be assessed in a timely manner.

## **Regulation 4DC Importation of vaporiser nicotine**

Regulation 4DC implements a prohibition on the importation of vaporiser nicotine. The provisions of regulation 4DC mirror those of regulation 4DB, with the following differences:

The provisions apply in relation to vaporiser nicotine. Vaporiser nicotine is defined in new subregulation 4DC(15) as nicotine in a solution, or in a base or salt form.

The exemption from prohibition for a passenger on board a ship or aircraft (provided in subregulation 4DC(3)) is limited by paragraph 4DC(3)(e). This provides that the exemption applies where the quantity of the vaporiser nicotine for use in a personal nicotine vaporiser imported is not more than three months' supply at the maximum dose recommended by the manufacturer (and the other requirements in subregulation 4DC(3) are met). This limits the amount of vaporiser nicotine that a passenger on a ship or aircraft may import without having to seek permission.

Subregulation 4DC(4) includes additional paragraph 4DC(4)(e). Paragraph 4DC(4)(e) provides that if an applicant for permission under subregulation 4DC(2) to import vaporiser nicotine is a person who is not a medical practitioner or sponsor to whom paragraph 4DC(4)(b), (c) or (d) apply, the application for permission must be made on the basis that the vaporiser nicotine is required for use by the applicant or another person solely for either scientific or industrial purposes.

The effect of this is to enable application for the importation of vaporiser nicotine for scientific or industrial use. For example, for use in laboratory analysis as a reference standard.

## **Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### **Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020**

This Disallowable Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Disallowable Legislative Instrument**

The purpose of the *Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020* (the Regulations) is to amend the *Customs (Prohibited Imports) Regulations 1956* (the PI Regulations) to implement a temporary prohibition on the importation of personal vaporisers such as e-cigarettes that contain nicotine in a solution, or in a base or salt form (either referred to as ‘vaporiser nicotine’), and vaporiser nicotine for a period of 12 months commencing on 1 July 2020.

It will be possible for the Secretary of the Department of Health, or an authorised person, to grant permission to import personal vaporisers such as e-cigarettes that contain vaporiser nicotine, and vaporiser nicotine. Applicants for permission will be either a medical practitioner or a sponsor who will be in effect a supplier of goods that meets requirements set out in the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act).

However, the possibility of applying for and being granted permission is not available for importation through the post, which is prohibited absolutely.

A person who is a passenger on board a ship or aircraft may import a personal vaporiser that contains vaporiser nicotine for personal use, without having to seek permission, if the vaporiser nicotine is for use in a personal vaporiser, is required for the medical treatment of the person or of another passenger under the care of the person and the use of the vaporiser nicotine in the personal vaporiser was prescribed by a medical practitioner and supplied in accordance with the prescription.

Similarly, a person who is a passenger on board a ship or aircraft may import a limited quantity of vaporiser nicotine that is for use in a personal vaporiser, is required for medical treatment of the person or of another person under their care, and the use of the vaporiser nicotine was prescribed by a medical practitioner and supplied for use with the personal vaporiser in accordance with the prescription.

Importing a prohibited import, such as vaporiser nicotine, without permission, is a strict liability offence pursuant to section 233 of the *Customs Act 1901*.

The temporary prohibition allows time for public consultation and advice from the ministerial expert Advisory Committee on Chemicals Scheduling and the Advisory Committee on Medicines Scheduling on a proposed amendment to the Poisons Standard, a legislative instrument made under the *Therapeutic Goods Act 1989*. The proposed amendment would

have the effect that nicotine products, including nicotine-containing e-cigarettes, would require a valid prescription (except for tobacco cigarettes or Therapeutic Goods Administration-approved smoking cessation products).

The proposal in this Disallowable Legislative Instrument has been discussed with the States and Territories which, consistently with their prohibition on domestic sale of e-cigarettes including vaporiser nicotine, support the prohibition on importation unless exempt in the specified circumstances. Reflecting the prohibition on domestic commercial supply, the prohibition on importation is not expected to affect Australian suppliers of devices, accessories and non-nicotine containing e-cigarettes. Further, persons will still be able to access nicotine-containing e-cigarettes and nicotine-containing e-cigarette fluids provided they have a relevant authority of a medical practitioner for smoking cessation purposes. In addition, the process for clarification of the appropriate schedule in the Poisons Standard of nicotine, which commenced in May 2020, is subject to its own rigorous consultation process under the *Therapeutic Goods Act 1989*.

### **Human rights implications**

This Disallowable Legislative Instrument engages the right to the enjoyment of the highest attainable standard of physical and mental health under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

The prohibition will assist in reducing the risk to public health through addiction to nicotine and nicotine poisoning.

#### *Risk of addiction*

There is currently insufficient evidence that nicotine-containing e-cigarettes are an effective cessation tool for current smokers. There are, however, significant risks associated with exposure to nicotine. It is highly addictive and there is a risk of nicotine dependence when used with e-cigarettes. There is strong evidence that nicotine-containing e-cigarettes, particularly those with added flavours, provide a gateway for adolescents and young adults to dependence on nicotine-containing e-cigarettes or to cigarette smoking. For example, in the USA, there was a 78 % increase in the numbers of high school children who are using e-cigarettes over the most recent 12-month period surveyed. This indicates that, without action, Australian youth may also be at risk.

#### *Risk of nicotine poisoning*

Nicotine is also highly toxic and poses significant health risks including adverse cardiovascular, respiratory and reproductive effects and negative effects on foetal and adolescent development. Ingestion of just 1-2 mL of nicotine in e-cigarette fluid refills, many of which have fruit or candy flavours and thus are attractive to children, can kill a toddler. There has been a significant increase in poisons centres calls following e-cigarette vaporiser ingestion by toddlers and children (200 in 2013-16), and several toddler deaths globally including one in Melbourne in June 2018.

Currently, the commercial sale of e-cigarettes containing vaporiser nicotine is prohibited in all States and Territories, and their possession is prohibited in four of the States and Territories. This new regulation will further strengthen Australia's precautionary approach to e-cigarettes by prohibiting the importation of nicotine for use in e-cigarettes or vaporisers unless exempt in specific circumstances. E-cigarette users, who in conjunction with their doctor believe that use of nicotine e-cigarettes can help them stop smoking can, under

prescription, still access the products. Access on a doctor's prescription means that their health can be appropriately monitored.

The amendment promotes the right to enjoyment of the highest attainable standard of physical and mental health under Article 12 of ICESCR, by restricting access to vaporiser nicotine as this limits the potential for people to become addicted to nicotine and limits the risk of nicotine poisoning.

To the extent that restricting the importation of vaporiser nicotine may adversely affect the health of current users, the prohibition in this amendment does not extend to persons who legitimately use vaporiser nicotine for a medical purpose or who bring a vaporiser or a limited quantity of vaporiser nicotine with them for personal use when entering Australia. Furthermore, persons in Australia are able to access vaporiser nicotine upon application by a medical practitioner in the treatment of that person. This ensures that persons who are being medically treated for their nicotine addiction can continue to access vaporiser nicotine in a controlled manner.

As such, while the measure will promote the right to health for the Australian community generally, where the measure may limit a person's rights, the limitation is necessary in order to protect the Australian community from the risks to health that misuse can cause, and is reasonable and proportionate as access to the substances is available where there is a legitimate medical need.

### **Conclusion**

The Disallowable Legislative Instrument is compatible with human rights because to the extent that the Disallowable Legislative Instrument limits Article 12 of the ICESCR the limitations are reasonable, necessary and proportionate.

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