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) Repeal Regulations 2020

The purpose of the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Repeal Regulations 2020 (the Regulations) is to repeal the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020 (the Vaporiser Nicotine Regulations).

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 Vaporiser Nicotine Regulations would have implemented a temporary prohibition on the importation of personal vaporisers such as e-cigarettes that contain nicotine in a liquid, base or a salt form (referred to as 'vaporiser nicotine'), as well as vaporiser nicotine on its own, for a period of 12 months commencing on 1 July 2020.

The Vaporiser Nicotine Regulations in effect would have prohibited the importation of nicotine containing e-cigarettes unless supported by a doctor's prescription. This prohibition was based on existing evidence and advice including from Australia's medical experts, such as the Australian Health Principal Protection Committee, which have warned of the health dangers of e-cigarettes containing vaporiser nicotine.

This is also consistent with the existing ban in all states and territories on the sale of ecigarettes containing vaporiser nicotine. Smoking rates in Australia have declined significantly over the past two decades, from 22.3 per cent in 2001 to 13.8 per cent in 2017-18. However, the latest statistics show tobacco use still contributed to an estimated 21,000 deaths, or more than one in eight, in 2015. In particular, around the world there is strong evidence of non-smokers being introduced to nicotine through vaping for the first time.

The Government therefore proposes to ensure that nicotine based e-cigarettes can only be imported on the basis of a prescription from a doctor for the purpose of assisting with preventing the introduction of non-smokers via use of vaporiser nicotine e-cigarettes.

However, there is a second group of people who have been using these e-cigarettes with nicotine as a means to ending their cigarette smoking. In order to assist this group to effectively transition to a prescription based access to e-cigarettes with nicotine, or to explore other options to end that addiction, the Vaporiser Nicotine Regulations have been repealed and a streamlined process for patients obtaining prescriptions through their GP is proposed to be established.

The proposed streamlining would require a change to what is known as the Authorised Prescriber scheme by which medical practitioners are authorised by the Therapeutic Goods Administration (the TGA) in the Department of Health to supply medicines which are not entered on the Australian Register of Therapeutic Goods. Although other therapeutic goods containing nicotine are entered on this Register, vaporiser nicotine is not. Generally, such authorisation requires evidence of approval from an ethics committee to supply the medicine for which authority to supply is requested.

From 25 June 2020, following the enactment of the *Therapeutic Goods Amendment (2020 Measure No. 1) Act 2020*, the *Therapeutic Goods Act 1989* provides authority to prescribe the circumstances in which a medical practitioner may gain authorisation from the TGA without requiring ethics committee approval to supply it.

The repeal of the Vaporiser Nicotine Regulations will also give patients time to anticipate their proposed delayed commencement by discussing with their GP the best way to give up smoking, such as using other products including patches or sprays. If e-cigarettes with nicotine are still required, patients will be able to gain a prescription.

Details of the Regulations are set out in <u>Attachment A</u>.

A Statement of Compatibility with Human Rights has been prepared in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*, and is at <u>Attachment B.</u>

Formal consultation was not undertaken due to the impending commencement of the Vaporiser Nicotine Regulations.

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

The whole of the Regulations commence on the day they are registered.

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<u>Details of the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Repeal Regulations 2020</u>

Section 1 – Name of Regulation

This section provides that the title of the Regulations is the *Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Repeal 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 the day it is registered.

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 is 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.

Schedule 1 – Repeals

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

Item 1 – The whole of the instrument

This item repeals the whole of the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020.

ATTACHMENT B

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) Repeal 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) Repeal Regulations 2020 is to repeal the Customs (Prohibited Imports) Amendment (Vaporiser Nicotine) Regulations 2020 (the Vaporiser Nicotine Regulations).

The Vaporiser Nicotine Regulations would have implemented a temporary prohibition on the importation of personal vaporisers such as e-cigarettes that contain nicotine in a liquid, base or a salt form (referred to as 'vaporiser nicotine'), as well as vaporiser nicotine on its own for a period of 12 months, commencing on 1 July 2020.

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This would give patients time to anticipate the proposed delayed commencement by discussing with their GP the best way to give up smoking, such as using other products

including patches or sprays. If e-cigarettes with nicotine are still required, patients will be able to gain a prescription.

Human rights implications

This Disallowable Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights, as it does not raise any human rights issues.

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