



Australian Government

Department of Health

Deputy Secretary

To Whom it may concern

The Australian Government has strengthened its stance against e-cigarettes containing nicotine

The Australian Government has announced today that they intend to ask the Governor-General in Council to amend the *Customs (Prohibited Import) Regulations 1956* from 1 July 2020 prohibiting the importation of e-cigarettes containing vapouriser nicotine (nicotine in solution or in salt or base form) and nicotine-containing refills unless on prescription from a doctor (see the **attached** media release).

If the Governor-General agrees to make the proposed regulations, from 1 July 2020, only doctors or medical suppliers would be able to import vapouriser nicotine-containing e-cigarettes or nicotine containing refills via a permission granted by the Department of Health. This would continue to allow individuals to use e-cigarettes including vapouriser nicotine if their doctor believes that they can assist with smoking cessation. It would also mean that an individual's health can be appropriately monitored.

This measure would further strengthen the Australian Government's precautionary approach to vapouriser nicotine-containing e-cigarettes and its commitment, including as a member of the Ministerial and Alcohol Drug Forum, to the protection of the health of children and young people. In this regard, it is instructive that in the USA, there was a 78 % increase in the numbers of high school children who are vaping over the most recent 12-month period surveyed. Nicotine poisonings have been on the rise and, at least in one case in Victoria in 2018, caused the death of a toddler.

The published evidence on whether vapouriser nicotine-containing e-cigarettes are effective in assisting smoking cessation is mixed and public health experts hold a range of views on the subject.

Individuals would be able to continue to use their personal nicotine vaporiser provided their doctor prescribes it for them and it is obtained on their behalf by a medical supplier, or obtained from a pharmacist who dispenses it for their use as the named patient. The company or the pharmacist would need to be given a copy of the prescription. Individuals would no longer be able to import the e-cigarette or, separately, the nicotine for use in their e-cigarettes directly from an overseas supplier. Other nicotine replacement therapies including sprays, patches, lozenges and chews will remain available.

The process by which an individual may get their personal nicotine vaporiser and what doctors, pharmacists and medical supply companies need to do to make that happen is set out in **Attachment A**.

Because vaporiser nicotine including when it is contained in an e-cigarette is a prescription only medicine, care needs to be taken to ensure that specific nicotine containing products are not advertised to the Australian public. To do so would risk committing a criminal offence under the *Therapeutic Goods Act 1989*. Whilst promoting such goods for sale would breach the law, factual and balanced statements about e-cigarettes containing nicotine, including the explanation of the benefits *as well as* the risks, would not. Promotion of smoking cessation services would also not cross this boundary. More information will be available shortly on the Therapeutic Goods Administration (TGA) website.

More information is included in the media release which will also shortly be reflected along with anticipated questions and answers on the TGA and the Office of Drug Control (Department of Health) websites.

If you would like further information please be in touch with Ms Jenny Francis, Principal Legal and Policy Adviser, Health Products Regulation Group, Department of Health: (02) 6289 4290 and jenny.francis@health.gov.au.

Yours sincerely



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