

## **Statement from the Federal Department of Health:**

**1. What reports of adverse events/side effects has the TGA received regarding the use of e-cigarettes in Australia in the last five years?**

**2. How many reported hospitalisations, lung transplantations and/or deaths have there been regarding the use of e-cigarettes in Australia in the last five years?**

The TGA has received a small number of adverse event reports related to nicotine vaping products. However, as an unapproved product, it is expected that many people who experience an adverse event may not report it to the TGA. The TGA has not received any reports of lung transplantation or death as a result of nicotine vaping liquids. We have received a small number of reports of hospitalisation, however the majority of these reports were associated with accidental exposure to the product, for example oral ingestion.

**3. What are the penalties for consumers for breaching the laws around e-cigarettes in Australia related to personal use or importation?**

**4. What are the penalties for retailers for breaching the laws around e-cigarettes in Australia related to the sale of products?**

Personal importation of nicotine vaping products such as e-cigarettes, and liquids containing nicotine for use with e-cigarettes without a valid written authority (for example a doctor's prescription) is an offence under the *Therapeutic Goods Act 1989*.

The TGA encourages consumers to comply with Australian laws by providing education and guidance in the first instance. The TGA will request the Australian Border Force seize any unlawful importations, including those intended for retail sale.

For repeated or deliberate non-compliance, the TGA takes escalated regulatory action which can include infringement notices, civil court proceedings and criminal prosecution.

It is an offence under section 19B of the Act to import and supply therapeutic goods without the relevant registration, listing, approval, authority or exemption. In addition, civil penalties can be imposed for the importation of such goods under section 19D of the Act.

The maximum penalty upon conviction is imprisonment for 5 years or a fine of up to \$888,000 or both for an individual, or a fine of \$4,440,000 for a body corporate in respect of each offence. Contravention of a civil penalty can attract maximum fines of \$1,110,000 for individuals and \$11,100,000 for a body corporate.

**5. How many retailers have been fined by the TGA for breaching the laws around e-cigarettes in Australia in the last five years?**

Since 1 October 2021, the TGA has issued 28 infringement notices, totalling \$266,4000 for the

alleged unlawful advertising and importation of NVPs.

## **6. How is the law in South Australia different regarding e-cigarettes compared to the rest of the country?**

There is nothing specific to South Australia, compared to the rest of the country, in the law regulating the supply and possession of nicotine vaping products. To the extent to which there was a difference in such regulation, it existed prior to 1 October 2021 and no longer applies. More information on the regulation of nicotine vaping products in South Australia since 1 October 2021 is available at this

link: <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/public+health/tobacco+and+e-cigarette+laws+and+businesses/tobacco+and+e-cigarette+laws+and+businesses>.

## **7. Have any prohibited ingredients been detected in e-cigarette products since October 1, if so please specify?**

Prohibited ingredients detected in the samples tested by the TGA since 1 October 2021 include diacetyl, 2,3-pentanedione, acetoin, ethylene glycol, benzaldehyde and trans-Cinnamaldehyde.

The TGA prohibits eight ingredients in nicotine vaping products that are known to pose known health risks when inhaled. Diacetyl (DAC); 2,3-Pentanedione (PDN); Acetoin (ACE); Ethylene glycol (EG); Benzaldehyde (BNZ); Diethylene glycol (DEG), vitamin E acetate (dl-alpha-tocopheryl acetate) and trans-Cinnamaldehyde (CIN).

## **8. What are the penalties related to prohibited ingredients being found in e-cigarette products in Australia?**

On 13 May 2021, the TGA made the [Therapeutic Goods \(Standard for Nicotine Vaping Products\) \(TGO 110\) Order 2021 \(TGO 110\)](#) under the *Therapeutic Goods Act 1989*. TGO 110 outlines the minimum safety and quality requirements for nicotine vaping products that are not registered in the Australian Register of Therapeutic Goods, and that are imported into, supplied in, or exported from Australia.

In particular, TGO 110 prohibits the use of certain substances as ingredients to a nicotine vaping product. These are known as “prohibited ingredients”, and are itemised in Schedule 1 to TGO 110. For further information, please refer to the TGA’s [Guidance for the Therapeutic Goods \(Standard for Nicotine Vaping Products\) \(TGO 110\) Order 2021 and related matters](#) (pages 19 – 22, in particular).

Where a person imports into, supplies in, or exports from Australia, nicotine vaping products that do not conform with the requirements in TGO 110, and the person does so without the written consent of the Secretary of the Department of Health, the person commits a criminal offence. Under the Act, the maximum penalty that can be imposed on an individual for such an offence is imprisonment for 5 years or \$888,000 (or both). Where the person convicted of this offence is a company, a Court

may impose a maximum pecuniary penalty of \$4.44 million.

A person who engages in conduct of this nature also contravenes a civil penalty provision of the Act, the maximum penalty for which is \$1.11 million (where the person is an individual) or \$11.1 million (where the person is a company).

Further, if it comes to the TGA's attention that a person has attempted to import or export nicotine vaping products that contain prohibited ingredients, without the written consent of the Secretary of the Department of Health, the TGA can also notify the Australian Border Force that it wishes the *Customs Act 1901* to apply to those goods. The effect of this is that the goods will be treated as prohibited imports or exports, and forfeited.