

The Senate

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Community Affairs Legislation  
Committee

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Therapeutic Goods and Other Legislation  
Amendment (Vaping Reforms) Bill 2024  
[Provisions]

May 2024

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# Abbreviations

The bill	The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024
The Committee	The Community Affairs Legislation Committee
Customs Act	<i>Customs Act 1901</i>
The Department	The Department of Health and Aged Care
ENDS	Electronic nicotine delivery systems
Industrial Chemicals Act	<i>Industrial Chemicals Act 2019</i>
The Minister	the Hon Mark Butler, Minister for Health and Aged Care
NRT	Nicotine Replacement Therapy
NVPs	Nicotine Vaping Products
Scrutiny Committee	Senate Standing Committee for the Scrutiny of Bills
The Secretary	The Secretary of the Department of Health and Aged Care
The Statement	The Statement of Compatibility with Human Rights
The Strategy	Australia’s National Tobacco Strategy 2023–2030
TGA	Therapeutic Goods Administration
Therapeutic Goods Act	<i>Therapeutic Goods Act 1989</i>
Tobacco and Other Products Act	<i>Public Health (Tobacco and Other Products) Act 2023</i>



# List of recommendations

## Recommendation 1

2.133 The committee recommends that the bill be passed.



# Chapter 1

## Introduction

- 1.1 The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the bill) was introduced by the Hon. Mark Butler, the Minister for Health and Aged Care, into the House of Representatives on 21 March 2024.<sup>1</sup>
- 1.2 On 27 March 2024, the Senate referred the provisions of the bill to the Community Affairs Legislation Committee (the committee) for inquiry and report by 8 May 2024.<sup>2</sup>

### Structure of the report

- 1.3 This report contains two chapters. This chapter sets out:
- the purpose of the bill;
  - background information relating to vaping reforms in Australia;
  - general information outlining the conduct of the inquiry and other committees' consideration of the bills; and
  - an overview of the key provisions of the bill.
- 1.4 Chapter 2 outlines inquiry participants' views on the bill and concludes with the committee's view and recommendation.

### Purpose of the bill

- 1.5 As articulated by the Hon Mark Butler, Minister for Health and Aged Care (the Minister), the intention of the bill is to:
- ... take strong action to ban the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods, except in very limited circumstances.<sup>3</sup>
- 1.6 The bill represents the second stage of the Australian Government's vaping reforms. The bill would extend the national system of controls for therapeutic goods under the Therapeutic Goods Act to include the regulation of vaping goods.<sup>4</sup>
- 1.7 As outlined in the Explanatory Memorandum, the bill:

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<sup>1</sup> *House of Representatives Votes and Proceedings*, No. 113, 21 March 2024, p. 1434.

<sup>2</sup> *Journals of the Senate*, No. 108, 27 March 2024, p. 3235; Senate Standing Committee for Selection of Bills, *Report No. 4 of 2024*, 27 March 2024, [p. 3].

<sup>3</sup> The Hon Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 2.

<sup>4</sup> Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, *Explanatory Memorandum* (Explanatory Memorandum), p. 7.

... provides a single consistent framework that applies nationally to regulate the importation, domestic manufacture, supply, commercial possession and advertisement of all vapes, irrespective of nicotine content or therapeutic claims.<sup>5</sup>

1.8 The bill would implement:

- a new framework for the regulation of vapes, enabling state and territory officials to undertake enforcement action;
- new offences and civil penalty provisions related to importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods; and
- enhanced existing compliance and enforcement powers in the Therapeutic Goods Act.<sup>6</sup>

1.9 As the Explanatory Memorandum highlights:

Bans on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods are intended to arrest and reverse the increasing uptake of recreational vaping, especially amongst youth and young adults by banning the domestic supply of vaping goods outside the pharmaceutical supply chain.<sup>7</sup>

## **Conduct of the inquiry**

1.10 Details of the inquiry were made available on the committee's website. The committee also contacted a number of organisations and individuals to invite written submissions by 12 April 2024.

1.11 The committee received 281 submissions, as listed at Appendix 1.

1.12 The committee held two public hearings in Canberra on 1 and 2 May 2024. A list of witnesses who gave evidence is included at Appendix 2.

1.13 In accordance with the committee's obligations under the World Health Organisation Framework Convention on Tobacco Control,<sup>8</sup> the committee did not accept confidentiality requests for submissions. Further, the committee required all witnesses to disclose any support they had received, whether financial or non-financial, direct or indirect, from any parties involved in the production, distribution or sale of tobacco, nicotine or vaping products.

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<sup>5</sup> Explanatory Memorandum, p. 1.

<sup>6</sup> Explanatory Memorandum, pp. 1–2.

<sup>7</sup> Explanatory Memorandum, p. 10.

<sup>8</sup> Department of Health and Aged Care, *WHO Framework Convention on Tobacco Control*, 14 December 2023, [WHO Framework Convention on Tobacco Control | Australian Government Department of Health and Aged Care](#) (accessed 4 April 2024). See also: Department of Health and Aged Care, [Guidance for Public Health Officials on Interacting with the Tobacco Industry](#), November 2019, p. 7.

## Note on references

1.14 References to *Committee Hansard* in this report are to proof transcripts. Page numbers may vary between proof and official transcripts.

## Note on terminology

1.15 Vaping products and devices have a range of different names; including but not limited to: e-cigarettes, mods, vapes, pod-mods and electronic nicotine delivery systems (ENDS). For the sake of consistency, this report will use the phrases vapes and vaping products.

## Acknowledgements

1.16 The committee thanks the organisations and individuals who contributed to the inquiry by making written submissions and giving evidence at the public hearings.

## Background

1.17 Australia has a long history of world-leading reforms in regards to tobacco control, including the first restrictions on tobacco advertising and more recent reforms such as plain packaging reforms for cigarettes.<sup>9</sup>

## Addressing a public health concern

1.18 In Australia, there has been a rapid rise in vaping among young people, contributing to a 'whole new generation of persons with nicotine dependence in our schools and our broader community'.<sup>10</sup>

1.19 The proliferation of vaping across the community represents a severe public health concern.<sup>11</sup> In particular, vaping has been associated with significant potential adverse effects, including on adolescent brain development, worsened pregnancy outcomes, cardiovascular disease, respiratory disease and cancer.<sup>12</sup> Vaping also carries other health risks such as severe burns, poisoning and seizures.<sup>13</sup>

1.20 There is also a marked increase in young people using vapes since 2017, with the latest national data showing that one in six secondary school students aged

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<sup>9</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 2.

<sup>10</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>11</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>12</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>13</sup> The Department of Health and Aged Care, *Submission 1*, p. 6.

12 to 17 years report recent vaping in 2022–23<sup>14</sup> and trend data showing that people aged 14 years currently using a vape had increased from 2.5 per cent to 8.9 per cent between 2020 and 2023.<sup>15</sup>

1.21 Further, many vapes are marketed as containing no nicotine or zero nicotine,<sup>16</sup> but the Therapeutic Goods Administration (TGA) has reported that approximately 90 per cent of tested vapes are found to contain nicotine, regardless of statements listed on the label.<sup>17</sup>

1.22 There has also been an increased risk with the potential co-occurrence of vaping and uptake of cigarette smoking:

Indeed, there is strong and consistent evidence that youth and young adults who vape are more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known. The highly addictive nature of nicotine, and the fact that vapes are inhaled into the lungs, mean the population-wide health risks of these products can be severe.<sup>18</sup>

### **Vaping and tobacco reforms in Australia**

1.23 Australia's National Tobacco Strategy 2023–2030 (the Strategy) establishes a framework for the Commonwealth, state and territory governments to coordinate work to reduce the prevalence of tobacco use.<sup>19</sup> The Strategy also includes a specific priority area related to enhanced regulation on e-cigarettes and emerging products.<sup>20</sup>

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<sup>14</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>15</sup> Explanatory Memorandum, p. 8.

<sup>16</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>17</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>18</sup> Explanatory Memorandum, p. 4.

<sup>19</sup> Department of Health and Aged Care, *Submission 1*, p. 2. See also: Department of Health and Aged Care, *National Tobacco Strategy 2023–2030*, 2 May 2023, [National Tobacco Strategy 2023–2030 | Australian Government Department of Health and Aged Care](#) (accessed 28 April 2024)

<sup>20</sup> Department of Health and Aged Care, *Submission 1*, p. 2.



- 1.24 This bill is designed as the second phase to the Australian Government’s vaping specific reform measures.<sup>21</sup> The first phase of vaping reforms involved amending a series of regulations within the remit of the TGA.<sup>22</sup>
- 1.25 With these regulation amendments, the importation of single-use vapes was banned on 1 January 2024, subject to very limited exceptions and the importation of all other vapes was banned on 1 March 2024, unless certain requirements were met in relation to those vapes under the *Therapeutic Goods Act 1989* (Therapeutic Goods Act).<sup>23</sup> The Minister described these reforms as ‘turning off the tap at the border as a necessary first step to combat supply’.<sup>24</sup>
- 1.26 The Australian Government is also implementing a range of actions to reduce use of tobacco and nicotine products through the National Tobacco Strategy 2023–2030.<sup>25</sup> The *Public Health (Tobacco and Other Products) Act 2023* commenced on 1 April 2024 and streamlines and modernises existing Commonwealth tobacco control laws, as well as extending advertising regulations to cover vaping goods.<sup>26</sup>
- 1.27 In May 2023, new tobacco excise measures were announced to reduce the affordability of tobacco products.<sup>27</sup> The government is also providing additional funding to services to encourage vaping and smoking cessation:
- \$29.5 million over four years for services that support quitting;
  - \$63.4 million for public health information campaigns to discourage Australians from taking up vaping or smoking and encourage quitting; and
  - \$141.2 million to extend the Tackling Indigenous Smoking program.<sup>28</sup>

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<sup>21</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>22</sup> Explanatory Memorandum, pp. 1–2. See also: Jennifer Phillips and Leah Ferris, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, *Bills Digest No. 61, 2023–24*, Parliamentary Library, Canberra, 2024, pp. 3–4.

<sup>23</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>24</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 3.

<sup>25</sup> Explanatory Memorandum, p. 5. See also: Department of Health and Aged Care, *National Tobacco Strategy*, 19 December 2023, [National Tobacco Strategy | Australian Government Department of Health and Aged Care](#) (accessed 9 April 2024).

<sup>26</sup> Explanatory Memorandum, p. 5.

<sup>27</sup> Explanatory Memorandum, p. 5. See also: The Hon. Mark Butler MP, Minister for Health and Aged Care, ‘Taking action on smoking and vaping’, *Media Release*, 2 May 2023.

<sup>28</sup> Explanatory Memorandum, p. 5.

### Vapes as a therapeutic good

1.28 The Minister explained the original introduction of vapes to the Australian market were designed for therapeutic use:

E-cigarettes and vapes were sold to governments and communities around the world as a therapeutic good—a product that could help hardened smokers, usually people in their 40s or 50s and beyond, to quit smoking and kick the habit.<sup>29</sup>

1.29 In seeking to recognise the purpose of these goods as therapeutic goods, the Minister commented that:

If vapes are therapeutic goods then it is entirely appropriate that Australia should regulate them as therapeutic goods, instead of allowing them to be sold alongside candy bars in convenience stores, often down the road from schools.<sup>30</sup>

1.30 Further, in recognition of the potential use of vapes as a therapeutic device, the Minister highlighted that:

Allowing patient access to therapeutic vapes strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to support Australians to quit smoking or manage nicotine dependence.<sup>31</sup>

### Consultation on the proposed reforms

1.31 The Department of Health and Aged Care (the Department) specified that the reforms were developed through a series of consultations since November 2022.<sup>32</sup>

1.32 Firstly, between 30 November 2022 and 16 January 2023, the TGA conducted a public consultation on proposed reforms to the quality standard for nicotine vaping products, with close to 4000 submissions received.<sup>33</sup>

1.33 Following this consultation and two Tobacco Control Roundtables, the TGA engaged with states and territories via the Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, which culminated in a

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<sup>29</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 2.

<sup>30</sup> The Hon. Mark Butler, Minister for Health and Aged Care and Deputy Leader of the House, *House of Representatives Hansard*, 21 March 2024, p. 2.

<sup>31</sup> Explanatory Memorandum, p. 11.

<sup>32</sup> Therapeutic Goods Administration, *Reforms to the regulation of vapes*, [Reforms to the regulation of vapes | Therapeutic Goods Administration \(TGA\)](#) (accessed 8 April 2024).

<sup>33</sup> Explanatory Memorandum, p. 6. See also: Therapeutic Goods Administration, *Proposed reforms to the regulation of nicotine vaping products*, 23 March 2023, [Proposed reforms to the regulation of nicotine vaping products - Therapeutic Goods Administration - Citizen Space \(tga.gov.au\)](#) (accessed 8 April 2024).

Health Ministers' Meeting Communique, outlining a collective commitment to enhancing regulation of vapes.<sup>34</sup>

- 1.34 In September 2023, the TGA undertook a second, targeted consultation on proposed reforms to the regulation of vapes developed in consultation with states and territories, as well as holding a series of webinars and stakeholder meetings.<sup>35</sup>

### **Financial impact statement**

- 1.35 The financial impact statement for the bill specifies that \$82.0 million will be provided over four years from 2023–24 to 'support the vaping reforms, awareness raising and enforcement activities'.<sup>36</sup> This funding includes:

- \$56.9 million over two years from 2023–24 to the Therapeutic Goods Administration to support regulatory development activities; and
- \$25.0 million over two years from 2023–24 to support the Australian Border Force's regulatory and enforcement activities.<sup>37</sup>

- 1.36 The financial impact statement further outlines that this bill would build on the Vaping Regulation Reform and Smoking Cessation Package measure from the 2023–24 Budget, which included allocation of \$511.1 million over four years from 2023–24. There was also \$101.1 million ongoing for activities including a national lung cancer screening program, nicotine vaping product regulation and reform, and cessation support activities for tobacco and vaping use.<sup>38</sup>

### **Compatibility with human rights**

- 1.37 The Statement of Compatibility with Human Rights (the statement) notes that the bill promotes and supports the following rights and international obligations:

- the right to health;
- the right to life;
- the obligation to ensure the survival and development of children; and

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<sup>34</sup> Explanatory Memorandum, p. 6. See also: Department of Health and Aged Care, [Health Ministers Meeting \(HMM\): Communique 1<sup>st</sup> September 2023](#), 2023, [p. 2].

<sup>35</sup> Explanatory Memorandum, p. 6. See also: Therapeutic Goods Administration, *Proposed reforms to the regulation of vapes*, 14 December 2023, [Proposed reforms to the regulation of vapes - Therapeutic Goods Administration - Citizen Space \(tga.gov.au\)](#) (accessed 8 April 2024).

<sup>36</sup> Explanatory Memorandum, p. 7.

<sup>37</sup> Explanatory Memorandum, p. 7.

<sup>38</sup> Commonwealth of Australia, *Budget Measures: Budget Paper No. 2 2023–24*, p. 154.

- the obligation to protect children from illicit use of narcotic drugs and psychotropic substances.<sup>39</sup>

1.38 The statement also highlights that the bill engages the following rights:

- the right to privacy;
- the right to freedom of expression;
- the right to a fair hearing;
- the right to the presumption of innocence;
- the right to be free from self-incrimination; and
- the right to not be tried or punished again for an offence for which a person has already been finally convicted or acquitted.<sup>40</sup>

1.39 The statement specifies that the bill is compatible with human rights because it supports and promotes a number of rights.<sup>41</sup> Furthermore, in regards to the limitations of certain rights that could occur as a result of the bill, the statement highlights:

...to the extent that the Bill limits any of these rights the limitations are reasonable, necessary and proportionate to achieving the aim of protecting public health by limiting access to harmful vaping goods.<sup>42</sup>

### **Consideration by other committees**

1.40 The Parliamentary Joint Committee on Human Rights made no comment on the bill in its Report 3 of 2024.<sup>43</sup>

1.41 The Senate Standing Committee for the Scrutiny of Bills (Scrutiny Committee) in its Scrutiny Digest No 5 of 2024 provided initial scrutiny of the bill, outlining concerns including:

- the significant matters to be included in delegated legislation;
- the strict liability offences; and
- the reversal of the evidential burden of proof.<sup>44</sup>

### **Definitions of commercial quantities and the evidential burden of proof**

1.42 Firstly, the Scrutiny Committee emphasised that the proposed offences within the legislation are contingent on the definition of a unit and a commercial

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<sup>39</sup> Explanatory Memorandum, p. 29.

<sup>40</sup> Explanatory Memorandum, p. 29.

<sup>41</sup> Explanatory Memorandum, p. 29.

<sup>42</sup> Explanatory Memorandum, p. 29.

<sup>43</sup> Parliamentary Joint Committee on Human Rights, *Report 3 of 2024*, 17 April 2024, p. 5.

<sup>44</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 12.

quantity of vaping goods, but these definitions are to be set out in regulations rather than the primary legislation.<sup>45</sup>

1.43 The Scrutiny Committee noted that the:

...definition of the commercial quantity is a central component to the offence provisions, with different penalties applying depending on the amount of the units above the commercial quantity in contravention.<sup>46</sup>

1.44 In emphasising its concern about this issue, the Scrutiny Committee made the following recommendation to the Minister:

The committee requests the minister's advice as to why it is necessary and appropriate for the definition of a 'unit' of vaping goods (in item 10 of Schedule 1) or the quantity of a kind of vaping goods that would amount to a commercial quantity (item 6 of Schedule 1) to be left to delegated legislation, noting the importance of these definitions to the offence provisions proposed to be inserted by the bill.<sup>47</sup>

1.45 Secondly, the Scrutiny Committee assessed the proposed inclusion of new offences within the Therapeutic Goods Act, noting that 'most if not all the new offences are being introduced alongside offence-specific defences which reverse the evidential burden of proof'.<sup>48</sup>

1.46 Of particular concern to the Scrutiny Committee was the issue of offences with strict liability elements which:

...removes the requirement for the prosecution to prove the defendant's fault. In such cases, an offence will be made out if it can be proven that the defendant engaged in certain conduct, without the prosecution having to prove that the defendant had the intention to engage in the relevant conduct or was reckless or negligent while doing so.<sup>49</sup>

1.47 The Scrutiny Committee emphasised the importance of clarification in regard to these issues by highlighting:

...while the statement of compatibility on human rights outlines the general circumstances relating to the imposition of strict liability on the offences generally, the committee's expectation is that the imposition of strict liability should be explained contextually against each of the relevant offences. This

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<sup>45</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 12.

<sup>46</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, pp. 12–13.

<sup>47</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 15.

<sup>48</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 13.

<sup>49</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 13.

is especially the case in relation to offences where more than 60 penalty units are being imposed, which is the case with many of the offences in the bill.<sup>50</sup>

- 1.48 The Scrutiny Committee further highlighted that the proposed new offences are accompanied by offence-specific defences which reverse the evidential burden of proof, interfering with common law rights.<sup>51</sup> The Scrutiny Committee noted the inclusion of explanation of each of the reverse burden defences in the Explanatory Memorandum. However, the Scrutiny Committee still maintained concerns that most of the cases mentioned may not be justified as an offence-specific defence, given they may not necessarily exist as knowledge only available to the defendant.<sup>52</sup>
- 1.49 In relation to these issues, the Scrutiny Committee drew the attention of senators to its scrutiny concerns.<sup>53</sup>

### **Broad discretionary powers**

- 1.50 The bill proposes to empower the Secretary of the Department of Health and Aged Care (the Secretary) to give consent to applications to manufacture, supply or possess vaping goods and to grant an application subject to conditions.<sup>54</sup>
- 1.51 The Scrutiny Committee highlighted concerns in relation to these powers, noting:
- ...there is no guidance on the face of the bill, nor in the explanatory memorandum, as to what criteria may be considered by the secretary when deciding whether to grant or refuse such an application, or in deciding which conditions to impose, if any. These concerns are heightened noting the relevant of consent granted under proposed subsection 41RC(1) to the offence provisions of the bill.<sup>55</sup>
- 1.52 As a result of these concerns, the Scrutiny Committee requested the advice of the Minister to the necessity and appropriateness of these broad ranging powers and what criteria might be considered by the Secretary in making decisions under proposed subsection 41RC(1).<sup>56</sup>

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<sup>50</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, pp. 13–14.

<sup>51</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, pp. 13–14.

<sup>52</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 14.

<sup>53</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 15.

<sup>54</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 15. Proposed section 41RC of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>55</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 15.

<sup>56</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 15.

- 1.53 In further regard to the discretionary powers to be granted to the Secretary, the Scrutiny Committee raised concerns with the proposed section 42YT of the Therapeutic Goods Act which would 'enable the secretary to issue enforceable directions under the TG Act [Therapeutic Goods Act] or an instrument made under the TG Act'.<sup>57</sup>
- 1.54 Of these proposed powers, the Scrutiny Committee was concerned that these:
- ...are significant measures for which there is no explanation or justification provided in the explanatory memorandum. The committee is particularly concerned that notices may be issued as the result of the secretary's 'reasonable belief' without any further guidance provided on the face of the bill or the explanatory memorandum as to the factors that may lead the secretary to form such a belief.<sup>58</sup>
- 1.55 The Scrutiny Committee requested the Minister's explanation for the criteria to be considered by the Secretary where there is a belief on reasonable grounds that a person is not complying with the Therapeutic Goods Act or its instruments, as well as whether independent merits review is available for directions issued under proposed subsection 42YT(2) of the bill and clear justification as to the reasoning if this is not available.<sup>59</sup>

### **Seizure of assets**

- 1.56 In regard to the proposed powers for the seizure of assets contained within the bill, the Scrutiny Committee sought clarification as to the power that specifies that the Secretary keep seized goods for the purposes of proceedings where the goods may form evidence.<sup>60</sup>
- 1.57 Particularly, the Scrutiny Committee highlighted the Guide to Framing Commonwealth Offences that outlines that seized material:
- ... should only be retained for as long as necessary, and that consideration should be afforded to whether use and derivative use immunity applies in relation to incidentally seized materials.<sup>61</sup>
- 1.58 The Scrutiny Committee sought the advice of the Minister as to 'whether it is intended that use and derivative use immunities apply to materials incidentally seized and retained under proposed section 52AAA of the bill'.<sup>62</sup>

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<sup>57</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 16.

<sup>58</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 16.

<sup>59</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 16.

<sup>60</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 17.

<sup>61</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 17.

<sup>62</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 17.

### Delegation of powers

1.59 The Scrutiny Committee noted the inclusion of delegated authority for issues of enforcement, forfeiture of things seized under search warrant and return or retention of things declared not be forfeited to representatives of state or territory departments and authorities.<sup>63</sup>

1.60 The Scrutiny Committee sought clarification as to the level of delegation intended by the legislation, noting discrepancies between the text of the bill and the Explanatory Memorandum.<sup>64</sup> Specifically the committee:

... requests the minister's advice as to the intended formulation of the delegation in proposed subsection 57(1A) of the Therapeutic Goods Act 1989. The committee's preference is for the delegation to be limited to the head of the relevant departments and administrative units.<sup>65</sup>

1.61 The ministerial response to the issues raised by the Scrutiny Committee was received by the Scrutiny Committee on 9 April 2024.<sup>66</sup> The response is due to be tabled in the Senate after the publication of this report. As such, it was not possible to outline the detail of the ministerial response in this report.

### Key provisions of the bill

1.62 The bill contains three schedules, which seek to amend legislation as follows:

- Schedule 1 – Amendment of the *Therapeutic Goods Act 1989* (Therapeutic Goods Act);
- Schedule 2 – Amendment of the *Customs Act 1901* (Customs Act); and
- Schedule 3 – Amendments of the *Industrial Chemicals Act 2019* (Industrial Chemicals Act) and the *Public Health (Tobacco and Other Products) Act 2023* (Tobacco and Other Products Act).<sup>67</sup>

1.63 The most significant amendments contained within the bill are those intended to be made to the Therapeutic Goods Act. Accordingly, Schedule 1 specifies the following proposed changes:

- Part 1 – Definitions and objects of Act;
- Part 2 – Regulation of vaping goods;
- Part 3 – Advertising relating to vaping goods;
- Part 4 – Enforceable directions and forfeiture;
- Part 5 – Entry, searches and warrants;
- Part 6 – Delegation and authorised persons;

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<sup>63</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 18.

<sup>64</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 18.

<sup>65</sup> Senate Standing Committee for the Scrutiny of Bills, *Scrutiny Digest 5 of 2024*, 27 March 2024, p. 18.

<sup>66</sup> Senate Standing Committee for the Scrutiny of Bills, *Ministerial Responses*, [Ministerial Responses – Parliament of Australia \(aph.gov.au\)](https://aph.gov.au) (accessed 30 April 2024).

<sup>67</sup> Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, pp. i–ii.



- Part 7 – Release of information;
- Part 8 – Laboratory testing;
- Part 9 – Approvals for certain part 3–2 exempt goods;
- Part 10 – Offences and civil penalty provisions for breach of condition of certain exemptions or approvals; and
- Part 11 – Other amendments.<sup>68</sup>

## **Amendments to the Therapeutic Goods Act**

1.64 The amendments contained within Schedule 1 of the bill are designed to expand the scope of the Therapeutic Goods Act to regulate all vaping goods, not just those that are designated as therapeutic goods.<sup>69</sup>

### **Part 1 – Definitions and objects of the Act**

1.65 The bill proposes to update the objects of the Therapeutic Goods Act to specifically include a national regulatory framework related to vaping, defined as follows:

(d) provide for the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are:

- (i) imported into Australia; or
- (ii) manufactured in Australia; or
- (iii) supplied in Australia, whether manufactured in Australia or elsewhere; or
- (iv) exported from Australia.<sup>70</sup>

1.66 The Minister may, by legislative instrument, determine that goods are therapeutic goods for the purposes of the Act.<sup>71</sup>

1.67 In considering whether to determine if goods are therapeutic goods for the purposes of the Act, the Minister must give regard to particular issues, including:

- the likelihood of the specified goods causing public health harm;
- the appropriateness of applying the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods under the Act to regulate the specified goods; and

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<sup>68</sup> Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, pp. i–ii.

<sup>69</sup> Explanatory Memorandum, p. 31.

<sup>70</sup> Proposed amended subsection 4(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>71</sup> Proposed subsection 7AAA(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

- whether the risks from the specified goods might be more appropriately dealt with under another regulatory scheme.<sup>72</sup>
- 1.68 The Minister may also have regard to any other relevant matter before making a determination under new subsection 7AAA(1).<sup>73</sup>
- 1.69 Of the proposed definitions, the Explanatory Memorandum explains:
- Allowing the definition of therapeutic goods to be broadened in delegated legislation will enable rapid amendments to cater for novel and unanticipated products that it is desired should be regulated as therapeutic goods. Despite the broad definition of therapeutic goods, the importation, manufacture, supply, export and advertising of goods in novel and unanticipated forms that should be regulated as ‘therapeutic goods’ may not readily fit within the current definition is still a possibility and may pose a risk to public health. This is intended to be a broad power for the Minister to specify any good to be a therapeutic good.<sup>74</sup>
- 1.70 Further, subsection 57(1) of the Therapeutic Goods Act allows the Minister to delegate this power to a broad range of delegates, which ‘ensures that those with the most relevant expertise in regulating new and emerging therapeutic goods can participate in the decision-making process’.<sup>75</sup>
- 1.71 Under the Therapeutic Goods Act, the Secretary of the Department can request information from individuals who have imported into Australia, or supplied in Australia, goods under the Act.<sup>76</sup> The bill would also expand the scope of the classes of person from whom the Secretary of the Department may request information from, to include the specification of goods that are therapeutic goods under the new section 7AAA(1), namely goods related to vaping.<sup>77</sup>

## **Part 2 – Regulation of vaping goods**

### *Defining and identifying vaping goods*

- 1.72 The bill would insert two definitions into the Therapeutic Goods Act: the definition of a ‘commercial quantity’ and the definition of ‘evidential burden’.<sup>78</sup>

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<sup>72</sup> Proposed subsection 7AAA(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>73</sup> New paragraph 7AAA(2)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 34.

<sup>74</sup> Explanatory Memorandum, p. 34.

<sup>75</sup> Explanatory Memorandum, p. 34.

<sup>76</sup> Subsection 8(1) of the Therapeutic Goods Act.

<sup>77</sup> Proposed paragraph 8(1)(ba) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 34.

<sup>78</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

The insertion of 'commercial quantity' into the Act references that a commercial quantity of a kind of vaping goods would be defined in regulations under the Act.<sup>79</sup> The insertion of the definition of evidential burden reflects the definition in section 13.3 of the Commonwealth Criminal Code.<sup>80</sup>

- 1.73 The bill seeks to amend the Therapeutic Goods Act to provide updated definitions for manufacture within the Act to include reference to vaping goods,<sup>81</sup> specific definitions for medical practitioner, nurse practitioner and pharmacist<sup>82</sup> and updated definitions of supply to include vaping goods.<sup>83</sup>
- 1.74 Another element related to definitions within the Therapeutic Goods Act is the proposed inclusion of a new definition of a 'unit' of vaping goods, which is to be prescribed by regulations under the Act.<sup>84</sup>
- 1.75 Further, the bill would insert new definitions for 'vaping accessory', 'vaping device', 'vaping goods' and 'vaping substance' into the text of the Therapeutic Goods Act.<sup>85</sup> The Explanatory Memorandum notes that these definitions broadly mirror the definitions inserted into the Customs (Prohibited Imports) Regulations 1956 (CPI Regulations) by the Customs Legislation Amendment (Vaping Goods) Regulations 2023.<sup>86</sup>
- 1.76 While the definitions of vaping accessory, device, goods and substance are specified within the bill, there is a proposed inclusion that expands the meaning of vaping goods where there is an 'implied or express representation' that the goods are intended to be utilised as vaping substances, accessories or devices.<sup>87</sup> This includes the presentation of the goods, such as name,<sup>88</sup> labelling and

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<sup>79</sup> Explanatory Memorandum, p. 35.

<sup>80</sup> Explanatory Memorandum, p. 35.

<sup>81</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>82</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>83</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>84</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>85</sup> Proposed amended subsection 3(1) and proposed new section 41P of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>86</sup> Explanatory Memorandum, p. 36.

<sup>87</sup> Proposed new subsection 41P(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>88</sup> Proposed new subparagraph 41P(2)(a)(i) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

packaging,<sup>89</sup> and/or any advertising or informational material related to the use or supply of the goods.<sup>90</sup> The purpose of this inclusion in the bill is clarified in the Explanatory Memorandum as ensuring that:

... there is no requirement for testing or identification by an expert to determine whether a good is a *vaping good*. Goods can be *vaping goods* solely on the basis of express or implied representations made through the presentation of the goods, including the name, labelling, packaging and any advertising or informational material associated with the goods.<sup>91</sup>

1.77 Further, the goods are taken to be presented as vaping goods even if the presentation is misleading or confusing as to the content, proper use or identification of the goods; or there is the suggestion that the goods have ingredients, components or characteristics that they do not have.<sup>92</sup> As the Explanatory Memorandum expands:

In practice, subsection 41P(2) will enable the offences in the new Chapter 4A to operate even if goods have inaccurate claims or are the subject of misleading marketing. Subsection 41P(2) is intended to prevent persons from evading the regulatory controls in Chapter 4A by:

- modifying the components or ingredients of vaping goods; or
- designing the vaping goods to make them difficult to identify or detect; or
- describing the goods in a way that conceals their purpose to an uninformed observer but signals the intended use to the user.<sup>93</sup>

1.78 The bill would establish the power for the Minister to determine via legislative instrument that goods are or are not, or when used, advertised or presented for use in a particular way, are or are not to be specified as vaping goods.<sup>94</sup> As the Explanatory Memorandum further elaborates:

The subsection 41P(3) is intended to allow the Minister to determine that goods are vaping goods despite those goods not otherwise meeting the definition of vaping goods provided in 41P(1). Such a power is crucial if the Government is to maintain parity with an ever-evolving market.<sup>95</sup>

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<sup>89</sup> Proposed new subparagraph 41P(2)(a)(ii) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>90</sup> Proposed new subparagraph 41P(2)(a)(iii) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>91</sup> Explanatory Memorandum, p. 39.

<sup>92</sup> Proposed paragraph 41P(2)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>93</sup> Explanatory Memorandum, p. 39.

<sup>94</sup> Proposed subsection 41P(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>95</sup> Explanatory Memorandum, p. 40.

1.79 The Explanatory Memorandum further specifies that the powers specified in proposed subsection 41P(3) can also be delegated to:

- the Secretary;
- an SES employee, who holds or performs the duties of, an SES Band 3 position in the Department; or
- a person who is registered, in a state or internal territory, as a medical practitioner and who holds or performs the duties of, a position that is equivalent to or higher than, an SES Band 2 position in the Department.<sup>96</sup>

1.80 The delegation of this power is designed to ensure the instruments are responsive to a ‘rapidly evolving market that has repeatedly sought to evade regulation’.<sup>97</sup> Given the time critical nature of this responsiveness, the Explanatory Memorandum specifies that ‘it is important to have a sufficient number of delegates, at a senior level available to make such an instrument’.<sup>98</sup>

### *Offences and civil penalty provisions*

1.81 The bill specifies offences and civil penalty provisions for the following activities:

- importing vaping goods into Australia;<sup>99</sup>
- manufacturing or carrying out a step in manufacturing vaping goods in Australia;<sup>100</sup>
- supplying vaping goods in Australia;<sup>101</sup>
- possessing at least commercial quantity but less than 100 times the commercial quantity;<sup>102</sup> and
- possessing a quantity of a kind of vaping goods in Australia where the quantity is less than the commercial quantity of that kind of vaping goods.<sup>103</sup>

1.82 The Explanatory Memorandum specified the policy intent, noting ‘the bans are intended to apply to all persons in the supply chain and ensure that supply is

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<sup>96</sup> Explanatory Memorandum, p. 75.

<sup>97</sup> Explanatory Memorandum, p. 75.

<sup>98</sup> Explanatory Memorandum, p. 75.

<sup>99</sup> Proposed section 41Q of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>100</sup> Proposed section 41QA of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>101</sup> Proposed section 41QB of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>102</sup> Proposed section 41QC of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>103</sup> Proposed section 41QD of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

through the legitimate pathways'.<sup>104</sup> Further, the Explanatory Memorandum commented that:

In relation to possession, the intent is not to criminalise or otherwise prohibit the personal possession of vaping goods. It is only commercial possession that is intended to be prohibited or possession other than for personal use.<sup>105</sup>

1.83 The offences and civil penalty provisions are designed in line with the remainder of the Therapeutic Goods Act, notably the Act:

... includes a tiered penalty regime for most offences, with two fault-based offences (one with an aggravated factor) and a strict liability offence. There is also usually a corresponding section which makes the relevant physical conduct a contravention of a civil penalty provision.<sup>106</sup>

1.84 The operation of offence provisions such as these 'gives regulators a choice of responses in respect of the same physical conduct and a range of enforcement options'.<sup>107</sup> Further:

Providing these options will enable the utilisation of a range of regulatory tools, including the issuing of an infringement notice, commencing civil penalty proceedings or criminal prosecution with a view to specifically and generally deterring the proscribed conduct.<sup>108</sup>

1.85 Further explaining the intention behind the varying tiers of offences contained within the bill, the Explanatory Memorandum elaborated that:

... the TGA would generally elect to deal with breaches by way of a criminal prosecution where there is an element of culpability. This is particularly so where there is an organised crime element to the offending. Where culpability and criminality of the conduct are not apparent but there is a need to address breaches of the Act and deter future non-compliance, it would be appropriate for the TGA to opt for a civil penalty fine, or other enforcement mechanism such as the giving of an infringement notice, accepting an enforceable undertaking or issuing a forfeiture direction.<sup>109</sup>

1.86 A summary of each of the offences and civil penalty provisions, including the maximum penalties, is outlined below.

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<sup>104</sup> Explanatory Memorandum, p. 41.

<sup>105</sup> Explanatory Memorandum, p. 41.

<sup>106</sup> Explanatory Memorandum, p. 41.

<sup>107</sup> Explanatory Memorandum, p. 41.

<sup>108</sup> Explanatory Memorandum, p. 41.

<sup>109</sup> Explanatory Memorandum, p. 42.

**Figure 1.1 New offences and civil penalty provisions with relevant maximum penalties**

Provision	Offence	Maximum penalty (fault-based offence)	Maximum penalty (strict liability offence)	Maximum penalty (civil penalty)
41Q	Importation of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QA	Manufacture of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QB	Supply of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QC	Possession of commercial quantity of vaping goods	For an individual— At least the commercial quantity – 2 years imprisonment/1,000 penalty units. At least 100 times the commercial quantity – 4 years imprisonment/3,000 penalty units. At least 1000 times the commercial quantity – 7 years imprisonment/5,000 penalty units. For a body corporate—	For an individual— At least the commercial quantity – 120 penalty units. At least 100 times the commercial quantity – 240 penalty units. At least 1000 times the commercial quantity – 420 penalty units. For a body corporate—	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
		At least the commercial quantity – 5,000 penalty units. At least 100 times the commercial quantity – 15,000 penalty units. At least 1000 times the commercial quantity – 25,000 penalty units.	At least the commercial quantity – 600 penalty units. At least 100 times the commercial quantity – 1,200 penalty units. At least 1000 times the commercial quantity – 2,100 penalty units.	
41QD	Possession of less than commercial quantity of vaping goods	For an individual—Imprisonment for 12 months and/or 500 penalty units. For a body corporate—2,500 penalty units.	For an individual—60 penalty units. For a body corporate—300 penalty units.	For an individual—1,000 penalty units. For a body corporate—10,000 penalty units.

Source: *Explanatory Memorandum*, pp. 47–48.

- 1.87 In discussing the significance of the penalties within the proposed bill related to vaping, the Explanatory Memorandum emphasises the proposed offences are similar to comparable existing offences within the Therapeutic Goods Act.<sup>110</sup>
- 1.88 Related to the civil penalties, the Explanatory Memorandum discusses the employment of fines and civil penalties as an appropriate alternative to criminal sanctions in some instances:

... civil penalties are appropriate in regulating commercial activities involving the importation, manufacture, supply and possession of a commercial quantity of vaping goods. This is particularly so where the relevant activities are undertaken by incorporated bodies, including subsidiaries of multinational companies engaged in commercial operations in Australia. The financial disincentive that a civil penalty regime provides

<sup>110</sup> Explanatory Memorandum, p. 43.

to address and deter breaches of the TG Act is likely to be more effect than criminal sanctions in appropriate circumstances.<sup>111</sup>

1.89 Moreover:

It is anticipated that the level of civil penalties will act as an effective financial disincentive against non-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available.<sup>112</sup>

### **Commonalities across the offence and civil penalty provisions**

#### *Separate contraventions for civil penalty provisions*

1.90 In relation to the civil penalty provisions for import, manufacture, supply and possession of vaping goods, each unit of vaping good would constitute a separate contravention.<sup>113</sup> The Explanatory Memorandum specified that defining a unit of vaping goods in the regulations is a deliberate measure to ensure 'there is clarity in the proscribed conduct in these provisions and avoid ambiguity and unintended consequences', such as treating singular amounts of vaping goods of vastly different volumes in the same manner.<sup>114</sup>

1.91 The Explanatory Memorandum outlined the flexibility of powers afforded to the Secretary of the Department:

Framing the civil penalty contraventions in this way, on a per unit approach will also allow the Secretary to give a person an infringement notice(s) as an alternative to having the penalty determined by the court and provides greater flexibility for the Secretary to decide an appropriate penalty amount.<sup>115</sup>

#### *Liability of CEOs and body corporates*

1.92 For each of the specified offences, there is also a note to section 54B. Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers who:

... are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches.<sup>116</sup>

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<sup>111</sup> Explanatory Memorandum, p. 44.

<sup>112</sup> Explanatory Memorandum, p. 45.

<sup>113</sup> Explanatory Memorandum, p. 45.

<sup>114</sup> Explanatory Memorandum, p. 45.

<sup>115</sup> Explanatory Memorandum, p. 45.

<sup>116</sup> Section 54B and 54BA of the Therapeutic Goods Act. See also: See also: Proposed sections 41Q, 41QA, 41QB, 41QC and 41QD of the Therapeutic Goods Act, Therapeutic Goods and Other



- 1.93 The Explanatory Memorandum specifies that this is a deliberate inclusion given the unique nature of vaping offences:

There is significant public harm from the importation of vaping goods into Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.<sup>117</sup>

### *Strict liability offences*

- 1.94 As specified in the table above, the bill proposes a maximum penalty for strict liability offences for each of the identified unlawful behaviours related to vaping. In relation to the inclusion of strict liability offences, the Explanatory Memorandum explains:

A strict liability offence has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.<sup>118</sup>

### *Exceptions for medicinal cannabis*

- 1.95 For each of the offences specified in the bill, the Explanatory Memorandum highlights that it would be likely that medicinal cannabis vapes would be subject to separate regulations. Particularly, it is noted that it is anticipated that the Minister would make a determination under proposed sections 41R and 41RA that would ‘determine indications appropriate for medicinal cannabis vapes’.<sup>119</sup>

### *Evidential burden of proof*

- 1.96 For all of the civil penalty provisions specified in this chapter of the bill, it is important to note that the burden of proof to provide evidence for reliance on an exception rests with the individual to prove. As the bill states:

If, in proceedings for a pecuniary penalty order against a person for a contravention of a civil penalty provision in this Chapter, the person wishes to rely on any exception, exemption, excuse, qualification or justification

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Legislation Amendment (Vaping Reforms) Bill 2024 and Explanatory Memorandum, p. 49, p. 51 and 53, pp. 60–61.

<sup>117</sup> Explanatory Memorandum, p. 49. See also: Proposed sections 41Q, 41QA, 41QB, 41QC and 41QD of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 and Explanatory Memorandum, p. 51 and 53, pp. 60–61.

<sup>118</sup> Explanatory Memorandum, p. 49. See also: Proposed subsections 41Q(2), 41QA(2), 41QB(2), 41QC(3), 41QC(6), 41QC(9) and 41QD(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 and Explanatory Memorandum, p. 52, 54, 62, 67 and pp. 60–61.

<sup>119</sup> Explanatory Memorandum, pp. 55–56. See also: Explanatory Memorandum, p. 58, p. 59, p. 67, p. 69, p. 71 and pp. 64–65.

that applies in relation to the civil penalty provision, then the person bears an evidential burden in relation to that matter.<sup>120</sup>

### **Detail of the specified offences and applicable exceptions**

1.97 Each of the offences included within the bill are specified alongside circumstances in which there could be relevant exceptions and the types of evidence that might be provided by an individual seeking an exception.

#### *Importation offences*

1.98 For the importation offences, exceptions to the application of these offences and civil penalty provisions would occur if the importation would not be prohibited under the Customs Act.<sup>121</sup> The person would bear an evidential burden in relation to the action not being prohibited under the Customs Act. As the Explanatory Memorandum clarified, this burden on the defendant is:

... evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.<sup>122</sup>

1.99 The Explanatory Memorandum outlined that:

A licence and permit would likely be the evidence a person would need to produce to avail themselves of the exception. Whether a person has an import licence and permit is a matter peculiarly within their knowledge.<sup>123</sup>

1.100 The importation of vaping goods is subject to a requirement under the CPI Regulations requiring the importer to hold a licence and permit.<sup>124</sup> A permit to import each specific type of vaping good is required.<sup>125</sup> Before an import permit can be granted under a vaping good import licence, the vaping good must be entered on the Register or a sponsor notice must be given to the Secretary which complies with applicable requirements under the Therapeutic Goods Act.<sup>126</sup>

1.101 A sponsor notice requires specification that a vaping good complies with applicable standards and is for smoking cessation or the management of

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<sup>120</sup> Proposed section 41QE of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>121</sup> Proposed subsection 41Q(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>122</sup> Explanatory Memorandum, p. 50.

<sup>123</sup> Explanatory Memorandum, p. 50.

<sup>124</sup> Explanatory Memorandum, p. 50.

<sup>125</sup> Explanatory Memorandum, p. 50.

<sup>126</sup> Explanatory Memorandum, p. 50.

nicotine dependence.<sup>127</sup> If a sponsor notice cannot be given as it does not meet these criteria, the importation and supply of the goods would be unlawful.<sup>128</sup>

1.102 A sponsor notice is not required for a vaping good to which a licence and permit under the CPI Regulations has already been granted and the TGA specified its intention to publish a list of vaping goods in relation to which sponsor notices have been given that can be made available for lawful supply.<sup>129</sup>

1.103 Under the CPI Regulations, a traveller's exemption also exists whereby persons entering Australia are allowed to carry no more than two vapes, 20 vape accessories and 200mL of vaping substance in liquid form.<sup>130</sup> Per the Explanatory Memorandum, this exemption 'gives effect to the intention not to criminalise possession of vaping goods for personal use'.<sup>131</sup>

### *Manufacturing offences*

1.104 Exceptions to the application of manufacturing offences and civil penalty provisions would be provided if the vaping goods are therapeutic goods<sup>132</sup> and one of the following applies:

- the person holds a licence authorising the manufacture of the vaping goods at the site where the manufacture takes place;<sup>133</sup>
- the person is the holder of a conformity assessment document that applies to the vaping goods;<sup>134</sup>
- the Secretary has given consent under subsection 41RC(1) to manufacture the vaping goods and the manufacture is undertaken in accordance with consent.<sup>135</sup>

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<sup>127</sup> Explanatory Memorandum, p. 51.

<sup>128</sup> Explanatory Memorandum, p. 51.

<sup>129</sup> Explanatory Memorandum, p. 51.

<sup>130</sup> Explanatory Memorandum, p. 51.

<sup>131</sup> Explanatory Memorandum, p. 51.

<sup>132</sup> Proposed subsection 41QA(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>133</sup> Proposed subparagraph 41QA(5)(b)(i) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>134</sup> Proposed subparagraph 41QA(5)(b)(ii) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>135</sup> Proposed subparagraph 41QA(5)(b)(iii) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

1.105 The evidential burden would rest with individual manufacturers to prove the eligibility of their activities in line with the above exceptions.<sup>136</sup> The Explanatory Memorandum outlined:

Whether a manufacturer has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.<sup>137</sup>

1.106 The requirement for the individual to be able to provide this evidence is further explained as necessary in this instance due to the situation where:

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.<sup>138</sup>

### ***Supply offences – unlawful vaping goods***

1.107 There are a range of exceptions that are specified within the bill regarding supply offences.<sup>139</sup> These include exceptions if the supply is part of the wholesale supply chain for prescription medicines or the retail supply chain.<sup>140</sup>

1.108 In instances of employing these exceptions for supply, the evidential burden rests with the supplier to provide sufficient documentation and evidence to demonstrate their involvement in supply of vapes is lawful.<sup>141</sup>

### ***Wholesale supply chain exceptions***

1.109 The exceptions related to the wholesale supply chain specify that the vaping goods being supplied must be:

- therapeutic goods that are included in the Register;<sup>142</sup> or

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<sup>136</sup> Proposed subsection 41QA(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 53.

<sup>137</sup> Explanatory Memorandum, p. 53.

<sup>138</sup> Explanatory Memorandum, p. 53.

<sup>139</sup> Proposed subsections 41QB(6), 41QB(7), 41QB(8), 41QB(9), 41QB(10) and 41QB(11) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>140</sup> Proposed subsections 41QB(6), 41QB(7), 41QB(8), 41QB(9), 41QB(10) and 41QB(11) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>141</sup> Explanatory Memorandum, pp. 54–50.

<sup>142</sup> Proposed paragraph 41QB(6)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

- exempt under the Therapeutic Goods Act,<sup>143</sup> the sponsor has given a notice in compliance with the exemption<sup>144</sup> and the vaping goods are not subject of a determination by the Secretary ceasing the supply of the goods;<sup>145</sup> or
- covered by a determination made by the Minister under the proposed section 41R of the Therapeutic Goods Act.<sup>146</sup>

1.110 The type of evidence that could be provided to demonstrate these exceptions include:

- a current certificate of registration of the vaping goods on the Register;
- a sponsor notification provided to the Secretary;
- evidence from the Department's website that the vaping good is not the subject of a determination; or
- a current determination applicable to the vaping goods made by the Minister.<sup>147</sup>

1.111 The bill specifies the potential exceptions available to people involved in the supply of vaping goods. These exceptions include a person who:

- is the holder of both a licence and a permission under regulations under the Customs Act or is otherwise approved under the regulations to import vaping goods;<sup>148</sup> or
- is the holder of a licence that authorises a step in manufacturing of vaping goods;<sup>149</sup> or
- is the holder of a conformity assessment document applying to vaping goods;<sup>150</sup> or

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<sup>143</sup> Proposed subparagraph 41QB(6)(b)(i) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 55. To be exempt under the Therapeutic Goods Act, the goods would need to be exempt in accordance with subsection 18(1) or under regulations made for the purposes of subsection 41HA(1) of the Therapeutic Goods Act.

<sup>144</sup> Proposed subparagraph 41QB(6)(b)(i) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>145</sup> Proposed subparagraph 41QB(6)(b)(ii) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>146</sup> Proposed paragraph 41QB(6)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>147</sup> Explanatory Memorandum, p. 56.

<sup>148</sup> Proposed paragraph 41QB(7)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>149</sup> Proposed paragraph 41QB(7)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>150</sup> Proposed paragraph 41QB(7)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

- is an authorised wholesaler and the supply occurs in accordance with their licence or authority;<sup>151</sup> or
- has received consent from the Secretary under proposed subsection 41RC(1) to supply the vaping goods and the supply occurs in accordance with the consent;<sup>152</sup> or
- where the goods are covered by a determination made under proposed section 41R of the Therapeutic Goods Act.<sup>153</sup>

1.112 The potential evidence that could be utilised in support of these exceptions are specified as the relevant licence, authority, consent or determination.<sup>154</sup>

1.113 In regards to the supply of vaping goods to a person, the bill outlines the circumstances in which an exception could be applied to recipients of vaping supply where the person:

- is a holder of a licence authorising a step in the manufacture of vaping goods;<sup>155</sup> or
- is a wholesaler, pharmacist, medical practitioner or nurse who holds a licence or is authorised to supply the substances where they practice their business;<sup>156</sup> or
- the Secretary has given to the recipient a consent under proposed subsection 41RC(1) to supply the vaping goods;<sup>157</sup> or
- the recipient is specified in a determination, or is included in a class of persons specified in the determination, made under proposed section 41R in relation to the goods.<sup>158</sup>

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<sup>151</sup> Proposed paragraph 41QB(7)(d) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>152</sup> Proposed paragraph 41QB(7)(e) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>153</sup> Proposed paragraph 41QB(7)(f) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>154</sup> Explanatory Memorandum, p. 56.

<sup>155</sup> Proposed paragraph 41QB(8)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>156</sup> Proposed paragraph 41QB(8)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>157</sup> Proposed paragraph 41QB(8)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>158</sup> Proposed paragraph 41QB(8)(d) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

1.114 Again, the Explanatory Memorandum specifies that the type of evidence a person is likely to produce as a defence includes the relevant licence, permission, authority, consent or determination.<sup>159</sup>

### *Retail supply chain exceptions*

1.115 The bill further outlines the exceptions to the offences and civil penalty provisions for supply as part of a retail supply chain.<sup>160</sup>

1.116 These exceptions are delineated depending on the specification of the vaping goods, the registration of the person supplying and the intention of the supply.<sup>161</sup>

1.117 An exception applies for the person supplying vaping goods if:

- the vaping goods are therapeutic goods entered on the Register;<sup>162</sup> or
- the vaping goods are exempt under the regulations, the sponsor has given the Secretary a notice in compliance with the exemption and the vaping goods are not the subject of a determination by the Secretary otherwise limiting supply;<sup>163</sup> or
- the vaping goods are covered by a determination made by the Minister.<sup>164</sup>

1.118 If the person is a pharmacist, or a medical practitioner or nurse practitioner who is authorised to supply a vaping substance, they could apply for the exceptions.<sup>165</sup>

1.119 Further, an exception is dictated where supply is provided by one person to another for use for smoking cessation or management of nicotine dependence, or to another person who is the carer for a third person for the use by that person for smoking cessation or management of nicotine dependence.<sup>166</sup> With this exception, the vaping goods must be in final dosage form, the supply must be

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<sup>159</sup> Explanatory Memorandum, p. 57.

<sup>160</sup> Explanatory Memorandum, p. 57.

<sup>161</sup> Proposed subsections 41QB(9), 41QB(10) and 41QB(11) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>162</sup> Proposed paragraph 41QB(9)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>163</sup> Proposed paragraph 41QB(9)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>164</sup> Proposed paragraph 41QB(9)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>165</sup> Proposed subsection 41QB(10) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>166</sup> Proposed paragraph 41QB(11)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

in accordance with the Therapeutic Goods Act and be consistent with the person's authority to supply the goods.<sup>167</sup>

1.120 In regards to the final dosage form, the bill provides that this is to mean the vaping substance exists in a form that can be administered to a person without any change or modification.<sup>168</sup>

***Banning the possession of at least a commercial quantity of vaping goods***

1.121 The bill would establish offences for the possession of commercial quantities of a kind of vaping goods, with exceptions in some circumstances.<sup>169</sup>

1.122 A commercial quantity of vaping goods is to be prescribed within regulations under the legislation.<sup>170</sup> The penalties for this offence type are specified in accordance with the amount of the commercial quantity.<sup>171</sup> Specifically, different penalties would apply on the basis of whether the quantity possessed is:

- at least a commercial quantity but less than 100 times the commercial quantity;<sup>172</sup>
- at least 100 times the commercial quantity but less than 1000 times the commercial quantity;<sup>173</sup> or
- 1000 times the commercial quantity or more of the kind of vaping goods.<sup>174</sup>

1.123 Of particular note in relation to these offences, the bill proposes to apply absolute liability to each of the offences.<sup>175</sup> As the Explanatory Memorandum outlines:

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to

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<sup>167</sup> Proposed subsection 41QB(11) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>168</sup> Proposed subsection 41QB(12) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>169</sup> Proposed section 41QC of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>170</sup> Explanatory Memorandum, p. 60. See also: proposed subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>171</sup> Explanatory Memorandum, p. 60.

<sup>172</sup> Proposed subsection 41QC(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>173</sup> Proposed subsection 41QC(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>174</sup> Proposed subsection 41QC(7) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>175</sup> Proposed subsections 41QC(2), 41QC(5) and 41QC(8) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.



establish a person's state of mind with respect to the quantity of vaping goods possessed.<sup>176</sup>

1.124 In continuation of the approach of the rest of the bill, there is the inclusion of a potential proposed offence of strict liability for each of the offences specified in relation to possessing at least a commercial quantity of a kind of vaping goods.<sup>177</sup>

1.125 The bill also includes a civil penalty provision for offences where the quantity of a type of vaping good is at least the commercial quantity.<sup>178</sup> The Explanatory Memorandum further specifies that:

A person is only liable for a civil penalty contravention of subsection (10) if they are in possession of a kind of vaping goods of at least a commercial quantity and the exceptions do not apply to them. Each contravention also takes into consideration each kind of vaping good in the possession of a person which is at least of a commercial quantity.<sup>179</sup>

1.126 For each unit of the quantity of vaping goods in a person's possession, there is deemed to be a separate contravention.<sup>180</sup> The Explanatory Memorandum explains that it is:

... intended that the per unit is to apply to each individual unit of vaping goods in the person's possession. For example, each vaping device, accessory or substance or combination thereof, would comprise of one unit for the purposes of calculating the number of contraventions.<sup>181</sup>

1.127 The Explanatory Memorandum also provides a relevant example of how these provisions would operate in practice:

Another example is if a person is found in possession of a large shipment of vaping goods and the shipment contains 5,000 vaping devices, 5,000 vaping substances and 5,000 vaping accessories (each of which exceed the prescribed commercial quantity), there will be 15,000 contraventions of subsection (10) in relation to the shipment; 5,000 contraventions in respect of each kind of vaping good.

This approach to the civil penalty provision is justified to achieve consistency across the other civil penalty prohibitions for import, manufacture and supply of vaping goods.<sup>182</sup>

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<sup>176</sup> Explanatory Memorandum, p. 60.

<sup>177</sup> Proposed subsections 41QC(3), 41QC(6) and 41QC(9) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>178</sup> Proposed subsection 41QC(10) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>179</sup> Explanatory Memorandum, p. 62.

<sup>180</sup> Proposed subsection 41QC(11) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>181</sup> Explanatory Memorandum, pp. 62–63.

<sup>182</sup> Explanatory Memorandum, p. 63.

1.128 Of the tiered penalties for criminal offences, the Explanatory Memorandum outlines:

Tiered penalties depending on the quantity of the vaping goods involved is appropriate in circumstances where there will be a wide spectrum of conduct captured under these offences. Tiered penalty structures also appear in other legislation such as Schedule 1 to the *Taxation Administration Act 1953* for possession of illicit tobacco and various offences under the Criminal Code.<sup>183</sup>

1.129 The exceptions for these possession offences are available where the vaping goods are:

- therapeutic goods on the Register;<sup>184</sup> or
- therapeutic goods that are exempt under regulations, the sponsor has provided a notice and the vaping goods are not otherwise banned through determination by the Secretary;<sup>185</sup> or
- covered by a determination made by the Minister.<sup>186</sup>

1.130 For individuals in possession of vaping goods, the exceptions could apply where the person:

- holds a licence or is approved under regulations to import vaping goods;<sup>187</sup> or
- holds a licence or is approved to manufacture vaping goods;<sup>188</sup> or
- holds a conformity assessment document;<sup>189</sup> or
- is authorised to supply the substances in accordance with Schedule 4 to the current Poisons Standard;<sup>190</sup> or

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<sup>183</sup> Explanatory Memorandum, p. 63.

<sup>184</sup> Proposed paragraph 41QC(13)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>185</sup> Proposed paragraph 41QC(13)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>186</sup> Proposed paragraph 41QC(13)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>187</sup> Proposed paragraph 41QC(14)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>188</sup> Proposed paragraph 41QC(14)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>189</sup> Proposed paragraph 41QC(14)(c) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>190</sup> Proposed paragraph 41QC(14)(d) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

- has been granted consent by the Secretary to possess the vaping goods;<sup>191</sup> or
- is specified or covered by a determination made by the Minister.<sup>192</sup>

### *Offences for possession of less than a commercial quantity of vaping goods*

1.131 The bill also seeks to establish tiered offences and civil penalty provisions for possession of less than a commercial quantity of vaping goods.<sup>193</sup> However, the Explanatory Memorandum to the bill explicitly states that this provision is not designed to target individual users, rather:

Section 41QD establishes offences and civil penalties for possessing a quantity of vaping goods less than the commercial quantity of that kind of vaping goods, with exceptions in certain circumstances including when the vaping goods are for personal use. The intention of these provisions is to deter persons possessing vaping goods less than a commercial quantity other than for personal use, including retailers or vendors who may be in possession of less than a commercial quantity of vaping goods in a retail setting not for personal use.<sup>194</sup>

1.132 For this section, the bill follows the standard protocol of offences and exceptions. Of particular note however, is the specification that provides an exception if the vaping goods are for personal use<sup>195</sup> or are possessed by an individual on behalf of another person for whom the vaping goods have been lawfully supplied.<sup>196</sup>

1.133 The Explanatory Memorandum dictates that this provision is deliberately included to give effect to ‘the intention not to criminalise possession of vaping goods less than a commercial quantity for personal use’.<sup>197</sup> Furthermore, the Explanatory Memorandum highlights:

The context and surrounding circumstances in which the vaping goods are possessed will likely be the primary factor which will determine whether this exception is available, such as whether the possession is in a retail setting. The type of evidence that a person is likely to produce to make out this subsection includes, but is not limited to, a prescription or written

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<sup>191</sup> Proposed paragraph 41QC(14)(e) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>192</sup> Proposed paragraph 41QC(14)(f) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>193</sup> Proposed section 41QD of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>194</sup> Explanatory Memorandum, p. 66.

<sup>195</sup> Proposed paragraph 41QD(9)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>196</sup> Proposed paragraph 41QD(9)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>197</sup> Explanatory Memorandum, p. 70.

authority to possess the vaping goods. However, such evidence is not necessary.<sup>198</sup>

1.134 Moreover, the Department further clarified:

Importantly, the controls in the Bill would not prohibit possession of vapes for personal use. The Bill would not penalise personal possession. Individuals will not be penalised for vaping. The Bill only seeks to prevent possession for the purposes of commercial supply.<sup>199</sup>

### **Determinations to be made by the Minister**

1.135 The bill would empower the Minister to determine specified vaping goods that may be supplied or possessed in Australia and the specific circumstances in which these goods would be exempt from the ban contained within the bill.<sup>200</sup> Such conditions the Minister may specify could include the value or amount of vaping goods or the manner in which the specified vaping goods could be supplied.<sup>201</sup>

1.136 As the Explanatory Memorandum outlines, this power is intended to:

... provide a mechanism by which the Minister can authorise the possession or supply of specified vaping goods by certain people in circumstances where they may not be authorised under other relevant statutory provisions. The Minister does not need to receive an application to decide whether to make a determination, however, there is nothing preventing a person from requesting that the Minister consider exercising the power in a particular circumstance.<sup>202</sup>

1.137 Further, the bill specifies that the Minister would be empowered to further classify via legislative instrument particular reasons (other than smoking cessation or management of nicotine dependence) for which vaping goods may be used.<sup>203</sup>

### **Consent of the Secretary**

1.138 If passed, the bill would empower the Secretary of the Department to provide consent for manufacture, supply or possession of vaping goods where an

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<sup>198</sup> Explanatory Memorandum, p. 70.

<sup>199</sup> Department of Health and Aged Care, *Submission 1*, p. 8.

<sup>200</sup> Proposed section 41R of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>201</sup> Proposed section 41R of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 71.

<sup>202</sup> Explanatory Memorandum, p. 71.

<sup>203</sup> Proposed section 41RA of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

application is made.<sup>204</sup> This would occur through an application via a form approved by the Secretary and the Secretary may write to the applicant to seek further information concerning the application.<sup>205</sup>

1.139 The Secretary would be empowered to grant consent unconditionally or subject to conditions for particular vaping goods or classes of vaping goods.<sup>206</sup>

1.140 Where the Secretary does provide consent, the bill proposes that the details of the decision are to be made available on the Department's website.<sup>207</sup> Where the Secretary refuses consent, written notice must be provided to the applicant within 28 days after making the decision with reasons outlining the decision taken.<sup>208</sup>

1.141 The bill also specifies offences and civil penalty provisions for situations where there is a breach of the conditions of consent approved by the Secretary under proposed section 41RC of the Therapeutic Goods Act.<sup>209</sup> The offences include 'a fault-based offence with an aggravating element'<sup>210</sup> where a person:

... commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1) and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.<sup>211</sup>

1.142 There is also provision for tiered offences, including a fault based offence, an offence of strict liability and civil penalty provisions for breaching the conditions of a consent provided by the Secretary.<sup>212</sup>

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<sup>204</sup> Proposed section 41RB of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>205</sup> Proposed subsections 41RB(2) and 41RB(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>206</sup> Proposed subsection 41RC(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>207</sup> Proposed subsection 41RC(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>208</sup> Proposed subsection 41RC(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>209</sup> Proposed section 41RD of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>210</sup> Explanatory Memorandum, p. 72. See also: proposed subsection 41RD(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>211</sup> Explanatory Memorandum, p. 72.

<sup>212</sup> Proposed section 41RD of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

1.143 The bill seeks to make a range of amendments to the Therapeutic Goods Act to provide updated references to the offences and definitions specified.<sup>213</sup>

1.144 The bill will also provide provision for evidence to be provided by the Secretary in relation to the civil penalty provisions, enabling:

... a certificate by the Secretary to the effect that the Secretary did not consent to the manufacture, supply or possession that is the subject of the proceedings, or consented to that manufacture, supply or possession subject to conditions specified in the certificate, is prima facie evidence of the matters specified in the certificate.<sup>214</sup>

1.145 The Explanatory Memorandum further explains the operation of this power:

Although this power, in effect, reverses the onus of proof, this reversal is considered reasonable in the circumstances. The existence of a consent is a matter of fact, that, outside of the Secretary's belief as expressed in a certificate, is peculiarly within the knowledge of the defendant. If the Secretary is of belief that the consent did, or did not exist, it is reasonable that only the defendant would be aware of the counter position. Adducing evidence to that effect would be most easily adduced by the defendant and would likely exist in the form of documentary evidence. The defendant need only meet an evidential burden of proof to rebut the certificate issued under 56A.<sup>215</sup>

### **Part 3 - Advertising restrictions related to vaping products**

1.146 The bill would seek to introduce a range of limitations on advertising related to vaping goods. As the Explanatory Memorandum outlines:

Advertising of vaping goods are absolutely prohibited in view of the health risks associated with vaping and the significant increase in the uptake of vaping in the last few years, in particular, by young people.<sup>216</sup>

1.147 While the bill intends to apply restrictions on advertising of vaping goods as far as possible, it also frames the mechanisms through which certain activities and behaviours are excluded. There is an exclusion that would be applied to advertisements that are exclusively intended for health practitioners, practice managers or people who are engaged in wholesale vaping businesses.<sup>217</sup> For the purposes of these exemptions the Minister may, by legislative instrument,

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<sup>213</sup> Explanatory Memorandum, pp. 73–74.

<sup>214</sup> Explanatory Memorandum, p. 74. See also: proposed subsection 56A(4B) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>215</sup> Explanatory Memorandum, p. 74.

<sup>216</sup> Explanatory Memorandum, p. 77.

<sup>217</sup> Proposed subsection 42DZ(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

specify the types of aforementioned individuals as exempt from the advertising limitations.<sup>218</sup>

1.148 The bill outlines that the advertising restrictions are also not applicable to health practitioners who are providing advice or information to their patient in the course of their treatment of that patient.<sup>219</sup> Moreover, the bill's provisions related to advertising are designed to apply in Australia; where advertisements are solely for vaping goods intended exclusively for export and the advertisements are not available in Australia, the provisions do not apply.<sup>220</sup>

1.149 The Explanatory Memorandum highlights that:

... there may legitimate reasons where advertising may in limited circumstances could be justified. For example, advertising for participants in a possible clinical trial, or advertising to discourage the use of vaping goods due to particular presence of an additive.<sup>221</sup>

1.150 As such, the Secretary of the Department is empowered through the bill to authorise advertising, or a class of advertising, of specified vaping goods.<sup>222</sup> The Secretary may also authorise the use of specific representations on the packaging, label or material within the packaging of the vaping goods if satisfied that the representations are necessary for the appropriate use of the goods.<sup>223</sup> In the event the Secretary pursues this course of action, the information must be made available on the Department's website specifying the authorisation given.<sup>224</sup>

### **Advertising offences**

1.151 The bill specifies these limited exemptions to the advertising ban, but then follows with clearly outlining the offences arising from engaging in unauthorised advertisement of vaping goods. Where a person advertises vaping

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<sup>218</sup> Proposed subsection 42DZ(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>219</sup> Proposed subsection 42DZ(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>220</sup> Proposed section 42DZA of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>221</sup> Explanatory Memorandum, p. 77.

<sup>222</sup> Proposed subsection 42DZC(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>223</sup> Proposed subsection 42DZC(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>224</sup> Proposed subsection 42DZC(6) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

goods that are not subject to an authorisation of the Secretary as specified above, the potential penalties include:

- imprisonment for 7 years or 5000 penalty units or both (for an offence);<sup>225</sup> or
- 200 penalty units (for an offence of strict liability).<sup>226</sup>

1.152 Further, where a person commits the above offences, for each day that they continue to advertise, it is considered a separate offence each day.<sup>227</sup> The maximum penalty for each day that an offence continues is 10% of the maximum pecuniary penalty.<sup>228</sup>

1.153 The Explanatory Memorandum justifies these powers by highlighting:

As supply and access of vaping goods are significantly influenced by advertising (including online advertising) and prohibition of advertising is an effective way of curbing and stopping supply, the high penalties are justified...<sup>229</sup>

1.154 Furthermore:

In assessing the level of penalties to be imposed it is considered that advertisements directed to minors (under 18's), advertisements of vaping goods close to schools and facilities, and advertisements indicating safety of vaping goods would attract the maximum penalty.<sup>230</sup>

1.155 The bill also specifies civil penalties where advertising of vaping goods occurs without authorisation or beyond the scope of the conditions of authorisation.<sup>231</sup>

### **Secretary's powers to seek further information**

1.156 The Secretary would be empowered to seek further information or documentation by written notice where a person appears responsible for

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<sup>225</sup> Proposed subsection 42DZD(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>226</sup> Proposed subsection 42DZD(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>227</sup> Proposed subsection 42DZD(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>228</sup> Proposed subsection 42DZD(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>229</sup> Explanatory Memorandum, p. 79.

<sup>230</sup> Explanatory Memorandum, p. 79.

<sup>231</sup> Proposed section 42DZE of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.



advertising<sup>232</sup> or providing generic information related to vaping goods.<sup>233</sup> The Explanatory Memorandum outlines this as an information gathering power, referred to as a ‘substantiation notice’.<sup>234</sup>

1.157 Following the provision of such a notice by the Secretary, if a person does not comply with the notice or gives false or misleading information, they may commit an offence or be liable to a civil penalty.<sup>235</sup>

1.158 The bill specifies the tiered scales of offences related to these notices, including a fault based offence and an offence of strict liability for failure to comply.<sup>236</sup> Where an individual deliberately gives false or misleading information there are stronger penalties specified within the bill, in comparison to those that are a result of a failure to comply with a notice.<sup>237</sup> There is also a civil penalty for individuals who provide false or misleading material that is produced under the auspices of complying with a notice.<sup>238</sup>

1.159 The bill proposes amendments to the Therapeutic Goods Act that ‘abrogates the privilege against self-incrimination in relation to the giving of information or producing a document’<sup>239</sup> where the Secretary requests it via notice. Specifically, a person is not excused from giving information or producing a document on the grounds that the information or document may incriminate them.<sup>240</sup>

1.160 The Explanatory Memorandum dictates the importance of this inclusion in the bill:

Without abrogating the privilege against self-incrimination, a person would withhold pertinent information that could seriously undermine the Secretary’s power to investigate possible contraventions of the TG Act or regulations and the ability to take timely regulatory action, criminal

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<sup>232</sup> Proposed subsection 42DZF(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>233</sup> Proposed subsection 42DZF(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>234</sup> Explanatory Memorandum, p. 81.

<sup>235</sup> Proposed subsection 42DZF(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>236</sup> Proposed subsections 42DZG(1) and 42DZG(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>237</sup> Proposed subsections 42DZG(3) and 42DZG(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>238</sup> Proposed section 42DZH of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>239</sup> Explanatory Memorandum, p. 82.

<sup>240</sup> Proposed subsection 42DZJ(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

prosecutions or civil penalty proceedings in relation to such contraventions.<sup>241</sup>

1.161 However, there are some exceptions that apply. In the case of an individual who provides information or a document; the information or document is not admissible in evidence against the individual except in relation to the more serious offences specified in the bill.<sup>242</sup>

1.162 When satisfied that there has been a contravention of the Therapeutic Goods Act or its regulations, the Secretary would also be empowered to direct a person responsible for advertising or generic information about vaping goods to:

- cease the advertisement or information;
- make a retraction;
- make a correction;
- recover any advertisement or information in circulation;
- destroy the advertisement or information;
- cease making a particular claim or representation contained in the advertisement or generic information.<sup>243</sup>

1.163 Where the Secretary gives a direction to a person under these powers, if the person does not follow the direction, the bill outlines a series of offences and civil penalties that can be enforced as a result.<sup>244</sup>

### **Public warning notices**

1.164 The Secretary can issue a public warning notice where there is a reasonable suspicion of a contravention of the Act in relation to advertising or generic information about vaping goods and the Secretary is satisfied it is in the public interest to issue the notice.<sup>245</sup>

1.165 Further, where an individual has been served with a substantiation notice by the Secretary and fails to comply, the Secretary may also issue a public warning notice about the person who has failed to comply that specifies the matter to which the original notice related.<sup>246</sup>

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<sup>241</sup> Explanatory Memorandum, p. 83.

<sup>242</sup> Proposed subsection 42DZJ(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>243</sup> Proposed subsections 42DZK(1) and 42DZK(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>244</sup> Proposed sections 42DZL and 42DZM of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>245</sup> Proposed subsection 42DZN(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>246</sup> Proposed subsection 42DZN(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

1.166 The bill would also seek to make a range of amendments across the text of the Therapeutic Goods Act for the purposes of consistency, reflecting the updated definition of advertise, as well as referencing the updated offence provisions specified in this section of the bill.<sup>247</sup> The bill would also include consistent references to the continuing contraventions specified above.<sup>248</sup>

#### **Part 4 - Enforceable directions and forfeiture**

1.167 The bill proposes a range of additional powers to be established under the Therapeutic Goods Act, to specify new forfeiture provisions, enforceable directions in relation to unlawful vapes and therapeutic goods and amendments extending authority for the issuing of warrants.<sup>249</sup>

1.168 Under the provisions of the bill, the Secretary would be empowered to give enforceable directions in relation to particular goods and in the event of a failure to comply with the direction, an individual may be liable for an offence or civil penalty.<sup>250</sup>

1.169 Where the Secretary believes, 'on reasonable grounds' that a person is not complying with the Act or its instruments in relation to particular goods<sup>251</sup> and there is a risk to the health and safety of humans,<sup>252</sup> the Secretary may direct the person to do any of the following, at their own cost:

- relabel or label the goods in compliance with the Act;
- repackage the goods in compliance with the Act;
- destroy or dispose of the goods;
- deliver the goods to a specified person to have them destroyed or disposed of appropriately; or
- any other thing prescribed by the regulations in relation to the goods.<sup>253</sup>

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<sup>247</sup> Explanatory Memorandum, pp. 88–90.

<sup>248</sup> Proposed subsections 42DLB(10A), 42DLB(10B), 42DMA(2A) and 42DMA(2B) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>249</sup> Explanatory Memorandum, pp. 92–93.

<sup>250</sup> Proposed section 42YS of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>251</sup> Proposed paragraph 42YT(1)(a) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>252</sup> Proposed paragraph 42YT(1)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>253</sup> Proposed subsection 42YT(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

- 1.170 Where a person is given a notice that they do not comply with, the bill specifies the applicable offences and civil penalty provisions.<sup>254</sup>
- 1.171 The Explanatory Memorandum elaborates that these powers are intended to give the Secretary ‘a broad range of compliance and enforcement tools to manage unlawful vapes and therapeutic goods generally’.<sup>255</sup>
- 1.172 In relation to the expanded forfeiture powers, the bill specifies that if items have been seized and the Secretary believes on reasonable grounds that the items have been imported, manufactured, supplied or possessed in contravention of the Act or its instruments, the item is forfeited to the Commonwealth.<sup>256</sup> The Explanatory Memorandum specifies the purpose of these powers:
- These enhanced forfeiture powers will enable the TGA to disrupt the trafficking of unlawful goods more efficiently, as well as address potential storage and destruction issues where large quantities of unlawful vapes are seized.<sup>257</sup>
- 1.173 Moreover, the Explanatory Memorandum elaborates that these powers:
- ... only apply where goods have been seized pursuant to a search warrant. The intention is that the Secretary would be empowered to initiate a process for the goods to be forfeited to the Commonwealth where there is a reasonable belief the goods have been unlawfully imported, manufactured, supplied or are otherwise non-compliant with the TG Act including in relation to possession.<sup>258</sup>
- 1.174 The Secretary must give a written forfeiture notice to the owner or person most recently identified in possession or control of the item immediately before seizure,<sup>259</sup> outlining the specifics of the seizure that has occurred.<sup>260</sup>
- 1.175 Where an individual was in possession of goods subject to a forfeiture notice, they are entitled to commence proceedings seeking to suspend the forfeiture from taking place.<sup>261</sup> These proceedings may commence prior to a forfeiture

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<sup>254</sup> Proposed subsections 42YT(4) and 42YT(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>255</sup> Explanatory Memorandum, p. 92.

<sup>256</sup> Proposed subsection 52AAA(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>257</sup> Explanatory Memorandum, p. 92.

<sup>258</sup> Explanatory Memorandum, p. 92.

<sup>259</sup> Proposed subsection 52AAA(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>260</sup> Proposed subsection 52AAA(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>261</sup> Proposed subsection 52AAA(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

notice being issued, but may only be commenced before the end of two months from the day the forfeiture notice is given.<sup>262</sup>

- 1.176 If such proceedings are not commenced or at the conclusion of proceedings a court has not made a declaration in regards to the item in question not being forfeited, it is automatically deemed to be forfeited to the Commonwealth.<sup>263</sup> The Secretary can then retain the item for purposes of the proceedings or cause for it to be disposed of as directed by the Secretary.<sup>264</sup>
- 1.177 The bill outlines circumstances where a thing can be declared to be not forfeited to the Commonwealth.<sup>265</sup> In the event a court declares that an item should not have been forfeited to the Commonwealth, an authorised person must take 'reasonable steps' to return the thing to the person from whom it was seized within 120 days.<sup>266</sup>
- 1.178 However, there are exceptions to this return of forfeited goods. The bill specifies situations where authorised persons may retain the items in question.<sup>267</sup> Further, the Secretary can specify terms and conditions of a return,<sup>268</sup> can make an application to an authorised person to retain the items for a further period<sup>269</sup> and can seek to retain the things for longer for the purpose of an investigation or as evidence for both civil penalties and offences.<sup>270</sup>

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<sup>262</sup> Proposed subsection 52AAA(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>263</sup> Proposed subsection 52AAA(6) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>264</sup> Proposed subsection 52AAA(6) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>265</sup> Proposed paragraph 52AAB(1)(b) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>266</sup> Proposed subsection 52AAB(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>267</sup> Proposed subsection 52AAB(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>268</sup> Proposed subsection 52AAB(4) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>269</sup> Proposed subsection 52AAB(5) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>270</sup> Proposed subsection 52AAB(6) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

1.179 If an issuing officer is satisfied it is necessary to retain the item for the purposes of an investigation or evidence, it can be kept for a period specified (not exceeding three years).<sup>271</sup>

## **Part 5 – Entry, searches and warrants**

1.180 The bill seeks to further extend the power to issue warrants and extension of time to retain seized goods to issuing officers.<sup>272</sup> Issuing officers are defined as a magistrate or registrar or other officer of a court of a state or territory who is authorised under law to issue search warrants.<sup>273</sup>

1.181 The Explanatory Memorandum dictates the purpose of these expanded powers, arguing:

The TGA often experiences operational [issues] when seeking timely access to magistrates to issue warrants. This is problematic when there is urgency in the obtaining and execution of a warrant. Consequently, these amendments extend the authority to issue monitoring, offence and civil penalty related warrants in relation to premises to court registrars and other legislative officers of a court of a state or territory.<sup>274</sup>

1.182 The bill proposes to make updated references throughout the Act, changing references from a ‘magistrate’ instead to an ‘issuing officer’.<sup>275</sup>

1.183 An issuing officer has their power conferred in a personal capacity and not as a court, member or officer of a court.<sup>276</sup> The issuing officer does not have to accept the power conferred.<sup>277</sup> However, an issuing officer exercising a power conferred by this part of the bill has the same protection and immunity as if they were exercising the power as the court or as a member or officer of the court.<sup>278</sup>

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<sup>271</sup> Proposed subsection 52AAB(6) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>272</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>273</sup> Proposed amended subsection 3(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 98.

<sup>274</sup> Explanatory Memorandum, p. 93.

<sup>275</sup> Explanatory Memorandum, pp. 98–100.

<sup>276</sup> Proposed subsection 51C(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>277</sup> Proposed subsection 51C(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>278</sup> Proposed subsection 51C(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

## Part 6 – Delegation and authorised persons

1.184 The bill seeks to achieve a ‘nationally consistent approach for the regulation of vaping goods by relying on the federal cooperative scheme for therapeutic goods’.<sup>279</sup> The Explanatory Memorandum explains that all states and territories have enacted corresponding laws to adopt the Commonwealth Therapeutic Goods Act and these laws ‘fill the gap in the Commonwealth’s constitutional power to ensure appropriate coverage for the regulation of therapeutic goods’.<sup>280</sup>

1.185 The bill seeks to make amendments to the Act to ‘empower state and territory officials to carry out enforcement powers under the new reforms’.<sup>281</sup> The bill would achieve this through the proposed powers of enforcement, forfeiture and retention of forfeited goods assigned to the Secretary<sup>282</sup> to be able to be further delegated to an officer of a state or territory authority.<sup>283</sup>

1.186 The bill specifies that the Secretary may delegate these powers via written instrument to an officer of:

- a Department of State of a State; or
- a Department or administrative unit of the Public Service of a Territory; or
- an authority of a State or of a Territory.

1.187 The Explanatory Memorandum specifies that this ‘Department, unit or authority must have functions relating to therapeutic goods, health or law enforcement’.<sup>284</sup> Further, the Explanatory Memorandum clarifies that:

In practice, the Secretary only provides authorisation and delegation of powers to officers who have the relevant skills and experience in relation to enforcement powers such as entry to premises, execution of search, monitoring and investigation warrants, testing of things and samples, and the seizing of evidential materials. Current delegates and authorised officers range from APS 5 to SES officers. Although delegation and authorisation are given to APS officers, they are generally accompanied by high level APS officers, and depending on the risks associated with the search and seizure, will be accompanied by law enforcement officers.<sup>285</sup>

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<sup>279</sup> Explanatory Memorandum, p. 102.

<sup>280</sup> Explanatory Memorandum, p. 102.

<sup>281</sup> Explanatory Memorandum, p. 102.

<sup>282</sup> These powers refer to those to be codified under the proposed chapter 5A and sections 52AA and 52AAB of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>283</sup> Proposed paragraph 57(1)(1A) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>284</sup> Explanatory Memorandum, p. 102.

<sup>285</sup> Explanatory Memorandum, p. 102.

1.188 A person exercising this authority must comply with any directions of the Secretary<sup>286</sup> and people to whom the power is further delegated must comply with any directions of the person who delegated the power.<sup>287</sup>

## **Part 7 – Release of information**

1.189 The existing section 61 of the Therapeutic Goods Act ‘principally provides for powers to release certain kinds of information to specified persons or the public, in certain circumstances’.<sup>288</sup> These powers are an ‘important mechanism’ that assists the Department to inform the public, health departments, law enforcement bodies and others of information, including safety and regulatory information within the remit of the Act.<sup>289</sup>

1.190 If passed, the bill would create new powers to:

... release information relating to vaping goods which mirror existing information release powers relating to therapeutic goods, and make consequential amendments to expand the application of section 61 to vaping goods.<sup>290</sup>

1.191 The Minister will be empowered via legislative instrument to authorise the release of vaping goods information to particular authorities or bodies, different types of authorities, different kinds of vaping goods information and for different purposes.<sup>291</sup> The Secretary will also be empowered to release particular vaping goods information following the establishment of such legislative instruments.<sup>292</sup>

1.192 The Minister can also specify via legislative instrument the type of information related to vaping goods that can be released to the public by the Secretary.<sup>293</sup>

1.193 The Explanatory Memorandum elaborates that these powers are intended to ‘provide flexibility for the release of a wide range of information relating to

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<sup>286</sup> Proposed subsection 7A(2) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>287</sup> Proposed subsection 57(12) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>288</sup> Explanatory Memorandum, p. 104.

<sup>289</sup> Explanatory Memorandum, p. 104.

<sup>290</sup> Explanatory Memorandum, p. 104.

<sup>291</sup> Proposed subsections 61(7A) and 61(7B) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>292</sup> Proposed subsections 61(7A) and 61(7B) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>293</sup> Proposed subsections 61(7C) and 61(7D) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.



vaping goods'.<sup>294</sup> The types of information could include public safety alerts about particular vaping goods, notices for law enforcement and health authorities about vaping goods suspected to be in contravention of the Act and public information about enforcement of regulations in relation to vaping goods.<sup>295</sup>

1.194 Under the Therapeutic Goods Act, therapeutic goods information provided to the Department in a manner may be used in consideration of another matter relating to therapeutic goods or given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods.<sup>296</sup> The bill seeks to expand this power to include information related to vaping goods.<sup>297</sup> The intention of this approach is to:

... ensure that information held by the Department in relation to a particular vaping-related matter (for example, intelligence about the kinds of prohibited vaping goods attempted to be illegally imported into Australia), may be used in relation to other functions, such as broader public health policy.<sup>298</sup>

## **Part 8 – Laboratory testing**

1.195 The bill seeks to expand 'existing regulation-making powers concerning the testing of therapeutic goods to include the testing of vaping goods (or any kind of goods, to ascertain whether the goods are vaping goods or therapeutic goods)'.<sup>299</sup>

1.196 Regulations exist which specify the procedures to be followed by the Department in the sampling and testing of therapeutic goods. The bill seeks to expand these testing powers to include vaping goods and any kind of goods for the purposes of ascertaining whether the goods are vaping goods or therapeutic goods.<sup>300</sup> The Explanatory Memorandum dictates that the phrase 'any kind of goods' has been especially included to 'capture a broad array of things, including physical possessions and digital possessions (like software)'.<sup>301</sup> Furthermore:

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<sup>294</sup> Explanatory Memorandum, p. 104.

<sup>295</sup> Explanatory Memorandum, p. 104.

<sup>296</sup> Subsection 61(8) of the Therapeutic Goods Act.

<sup>297</sup> Proposed amended subsection 61(8) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>298</sup> Explanatory Memorandum, p. 106.

<sup>299</sup> Explanatory Memorandum, p. 108.

<sup>300</sup> Proposed amended paragraph 63(2)(d) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>301</sup> Explanatory Memorandum, p. 108.

This amendment is intended to expressly permit the making of procedures related to obtaining and testing samples of kinds of goods where, for example, it is not apparent that the goods are therapeutic goods or vaping goods until after they have been sampled and tested, or where sampling and testing would be preferable to confirm a suspicion that the goods are therapeutic goods or vaping goods.<sup>302</sup>

1.197 Regulations made for the purposes of paragraph 63(2)(d) that are in force immediately before commencement will continue in force for the purposes of the paragraph as in force after its commencement.<sup>303</sup> This will maintain the existing regulations established prior to this bill.

1.198 The bill also specifies that the existing regulation making power in relation to testing of therapeutic goods, inspection of manufacturing operations or evaluation of data concerning therapeutic goods are all to be amended to also include vaping goods.<sup>304</sup>

### **Part 9 – Approvals for certain Part 3-2 exempt goods**

1.199 Under the current operation of the Therapeutic Goods Act, the Secretary is able to grant approval for importing into Australia or exporting from Australia of specified therapeutic goods that are not registered, listed or exempt goods.<sup>305</sup> This relates to goods for use for either treatment or experimental purposes in humans.<sup>306</sup> The Act specifies that regulations may exempt specified therapeutic goods to enable ‘the regulations to specify therapeutic goods, or classes of therapeutic goods, that may be imported into, manufactured in, and supplied in Australia, despite the goods not being included in the Register’.<sup>307</sup>

1.200 Currently, therapeutic vaping goods are only exempt goods if they are only for smoking cessation or the management of nicotine dependence and they are to be supplied to the ultimate consumer in accordance with approval or authority under section 19 of the Act, such as through the Authorised Prescriber Scheme.<sup>308</sup>

1.201 In order to address this potential issue, the bill seeks to amend the Therapeutic Goods Act to remove the reference to ‘exempt goods’ to ensure that ‘the lawful supply of therapeutic vapes under the relevant exemption’<sup>309</sup> can operate in line

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<sup>302</sup> Explanatory Memorandum, p. 108.

<sup>303</sup> Explanatory Memorandum, p. 109.

<sup>304</sup> Proposed amended paragraph 63(2)(g) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>305</sup> Subsection 19(1) of the Therapeutic Goods Act.

<sup>306</sup> Subsubsection 19(1) of the Therapeutic Goods Act.

<sup>307</sup> Explanatory Memorandum, p. 110. See also: subsection 18(1) of the Therapeutic Goods Act.

<sup>308</sup> Explanatory Memorandum, p. 110.

<sup>309</sup> Explanatory Memorandum, p. 110.

with the existing powers of the Secretary to determine importation or export approvals for the purposes of clinical trials or treatment.<sup>310</sup>

1.202 As the Explanatory Memorandum explains, the operation of these provisions:

... impacts the flexibility of the exemption for therapeutic vaping goods, as it establishes a barrier to legitimate patient access to such goods for smoking cessation, and the management of nicotine dependence, under appropriate clinical supervision.<sup>311</sup>

### **Part 10 – Offences and civil penalty provisions for breach of condition of certain exemptions or approvals**

1.203 Where an individual is operating with an exemption under the regulations specified throughout the Act and then acts or omits to act in a manner that results in a breach of a condition of their exemption, the bill seeks to establish offence and penalty provisions as a method for enforcement.<sup>312</sup>

1.204 The bill also seeks to make a range of amendments across the Act to reflect the updated legislative enforcement mechanisms where individuals or corporations breach a condition of an exemption.<sup>313</sup>

### **Part 11 – Other amendments**

1.205 Under the existing powers of the Therapeutic Goods Act, the Secretary is able to issue export certification for goods for therapeutic use in humans.<sup>314</sup> A state or territory must not issue similar export certifications.<sup>315</sup> The bill seeks to add provisions to the Act that specify that these powers be applicable to vaping goods.<sup>316</sup>

1.206 The Explanatory Memorandum further elaborates that fees may be prescribed for an application for such a certification or the inspection of a manufacturing site if necessary for the purposes of issuing such a certification.<sup>317</sup>

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<sup>310</sup> Proposed amended subsection 19(1) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>311</sup> Explanatory Memorandum p. 110.

<sup>312</sup> Proposed subsection 22(6), amended subsection 22(7AA), amended section 22AA, amended subsection 41MN(9) and proposed subsection 41MNA(2A) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, pp. 111–114.

<sup>313</sup> Explanatory Memorandum, pp. 111–114.

<sup>314</sup> Subsection 58(1) of the Therapeutic Goods Act.

<sup>315</sup> Explanatory Memorandum, p. 115.

<sup>316</sup> Proposed subsections 58(2A) and 58(2B) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>317</sup> Explanatory Memorandum, p. 115.

1.207 The current operation of the Therapeutic Goods Act ‘provides the Commonwealth and protected persons with immunity from civil actions or proceedings in certain circumstances’.<sup>318</sup> Specifically, a protected person is protected from civil action where another person suffers loss, damage or injury, if the protected person is acting in the exercise of their powers under the Act or its regulations.<sup>319</sup>

1.208 The Act specifies such ‘protected persons’, including the Minister, the Secretary and people who have had the power of Minister or Secretary delegated under the Therapeutic Goods Act.<sup>320</sup> However, the Explanatory Memorandum specifies that the list of protected persons ‘does not include all persons who may perform or exercise a function, duty or power under the TG Act or its regulations’.<sup>321</sup>

1.209 As such, the bill intends to include a reference to ‘a person of a kind prescribed by the regulations’ within the list of protected persons.<sup>322</sup> The justification for this inclusion is to:

... ensure that, for example, any new category of persons empowered to perform functions under the regulations may be subject to the immunity (by disallowable regulation), without the need for a commensurate amendment to the TG Act.<sup>323</sup>

1.210 Further amendments are subsequently proposed throughout the Act to substitute ‘an APS employee in the Department’ to be replaced by ‘a protected person’.<sup>324</sup> The Explanatory Memorandum elaborates that these inclusions are to:

... provide flexibility to, by regulation, broaden the range of persons that are protected from criminal responsibility when carrying out certain investigatory actions under the TG Act or its regulations.<sup>325</sup>

1.211 It is further explained that this is intended to provide protection to officials of states and territories, in order to ensure effective enforcement of vaping

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<sup>318</sup> Explanatory Memorandum, p. 115. See also: subsection 61A(1) of the Therapeutic Goods Act.

<sup>319</sup> Explanatory Memorandum, p. 115.

<sup>320</sup> Explanatory Memorandum, p. 115. See also: subsection 61A(4) of the Therapeutic Goods Act.

<sup>321</sup> Explanatory Memorandum, p. 115.

<sup>322</sup> Proposed paragraph 61A(4)(ga) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>323</sup> Explanatory Memorandum, p. 116.

<sup>324</sup> Proposed amended subsections 62(1) and 62(2), proposed new subsection 62(3) of the Therapeutic Goods Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>325</sup> Explanatory Memorandum, p. 116.

reforms.<sup>326</sup> Particularly the Explanatory Memorandum provides the following example of the operation of these powers in practice:

For example, a state or territory official may seize or purchase vaping goods within their jurisdiction, and then arrange for the same to be conveyed to the TGA for testing. As section 62 of the TG Act does not currently apply in relation to such cases, the relevant official may be prohibited from doing so (particularly if the goods contain, or are, prescription medicines).

Consequently, it is necessary to extend the protection that is provided by section 62 so that it also applies to persons other than APS employees in the Department. The amendments made by these items give effect to this measure, by providing flexibility to, by disallowable regulation, prescribe kinds of persons as protected persons.<sup>327</sup>

## **Schedule 2 – Amendment of the Customs Act**

1.212 Through amendments to the CPI Regulations, vaping goods have already been specified as prohibited imports for the purposes of the Customs Act since 1 January 2024.<sup>328</sup> Further, prohibited imports fall in the definition of ‘special forfeited goods’, meaning they can be seized with or without a warrant in certain circumstances.<sup>329</sup> The definition has deliberately been included in disallowable regulations to enable flexibility of definitions to adapt to the shifts in the illicit vaping goods market.<sup>330</sup>

1.213 Currently, under the Customs Act goods that are prohibited seized imports must be stored for a minimum of 30 days before they can be disposed of.<sup>331</sup> Further, a seizure notice must be served on the owner or person in possession of the goods who can subsequently make a claim for return of the seized goods within 30 days, otherwise they are taken to be forfeited to the Commonwealth.<sup>332</sup>

1.214 However, under the existing provisions of the Customs Act, certain goods may be dealt with outside of this process. Particularly, where goods are seized under the Customs Act and the Comptroller-General of Customs is satisfied they are a prohibited psychoactive substance, tobacco products or a prohibited serious drug alternative, the Comptroller-General can deal with them in an appropriate manner – including destruction.<sup>333</sup>

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<sup>326</sup> Explanatory Memorandum, pp. 116–117.

<sup>327</sup> Explanatory Memorandum, pp. 116–117.

<sup>328</sup> Explanatory Memorandum, p. 118.

<sup>329</sup> Explanatory Memorandum, p. 118.

<sup>330</sup> Explanatory Memorandum, p. 120.

<sup>331</sup> Explanatory Memorandum, p. 118.

<sup>332</sup> Explanatory Memorandum, p. 118.

<sup>333</sup> Explanatory Memorandum, p. 118.

1.215 The bill proposes to include vaping goods in a similar list of specified seized goods able to be dealt with differently to the standard procedures for seized goods where the Comptroller-General is satisfied the goods are prohibited imports.<sup>334</sup> As the Explanatory Memorandum explains:

Applying this approach to seized vaping goods will significantly enhance the ability of Australian Border Force officials to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.<sup>335</sup>

1.216 The bill also specifies provisions that following the goods in question having been dealt with or destroyed, no later than seven days after the Comptroller-General must publish a notice identifying the goods, the mechanism through which they were seized and how they have been dealt with.<sup>336</sup>

1.217 Further, the bill proposes amendments to the Customs Act to articulate the mechanisms for recourse for vaping goods owners who wish to dispute the circumstances of their destruction.<sup>337</sup> As dictated in the Explanatory Memorandum:

The purpose of this clause is to permit the owners of ‘vaping goods’ destroyed under subsection 206(2B) the right to recover the market value of the goods, if they can establish that the circumstances required to trigger the destruction did not exist.<sup>338</sup>

### **Schedule 3 – Amendment of other Acts**

1.218 The bill will also make amendments to the Industrials Chemicals Act and the Tobacco and Other Products Act.

1.219 For the Industrial Chemicals Act, the phrase ‘vaping goods’ will be inserted.<sup>339</sup> This is to ensure that ‘vaping goods are included in the exception of chemicals that are not industrial chemicals, such as chemicals for therapeutic purposes’.<sup>340</sup>

1.220 Further, a new paragraph is inserted to specify that the definition of industrial use for the purposes of the Industrial Chemicals Act ‘means a use other than (or

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<sup>334</sup> Proposed subsection 206(2B) of the Customs Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>335</sup> Explanatory Memorandum, p. 118.

<sup>336</sup> Proposed amended subsection 206(3) and proposed amended paragraph 206(5)(c) of the Customs Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>337</sup> Proposed amended subsections 206(6) and 206(7) of the Customs Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>338</sup> Explanatory Memorandum, p. 122.

<sup>339</sup> Proposed amended section 8 of the Industrial Chemicals Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>340</sup> Explanatory Memorandum, p. 123.

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in addition to) use as a vaping good (within the meaning of the TG Act) or in the preparation of such a good'.<sup>341</sup>

- 1.221 For the Tobacco and Other Products Act, amendments are proposed to include reference to the proposed new Part 5-1A of the Therapeutic Goods Act, which would regulate advertising and information related to vaping goods.<sup>342</sup>
- 1.222 Further, the bill seeks to amend the Tobacco and Other Products Act to specify vaping goods to be included as therapeutic goods for the purposes of that Act.<sup>343</sup>

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<sup>341</sup> Explanatory Memorandum, p. 123. See also: proposed new paragraph 9(da) of Industrial Chemicals Act, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.

<sup>342</sup> Proposed amended section 64 of the Public Health (Tobacco and Other Products) Act 2023, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 123.

<sup>343</sup> Proposed amended section 64 of the Public Health (Tobacco and Other Products) Act 2023, Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024. See also: Explanatory Memorandum, p. 123.





## Chapter 2

### Views on the bill

- 2.1 Overall, submitters supported the intent of the bill and particularly welcomed all measures aimed at curbing the emerging epidemic of vaping among young people and children.<sup>1</sup> Inquiry participants expressed grave concerns about increased rates of vaping use and recognised the importance of ensuring the legislation closes the current loophole, which has seen the proliferation of vaping products laced with nicotine, which are sold as non-nicotine vapes.<sup>2</sup> Health experts supported the proposed model, which supports legitimate patient access to therapeutic vapes. A number of submitters, including former smokers who now vape, expressed concerns about the proposed model and put forward alternative models to regulate vaping products in Australia.<sup>3</sup>
- 2.2 Firstly, the chapter discusses the risks and harms of vaping, especially on young people and children and how the proposed legislation will address these issues, including addressing the aggressive marketing of vaping products aimed at young people.
- 2.3 Then the chapter explores the proposed model, which enables smokers to access vapes as a cessation tool. It examines the way people will access vapes, the benefits of the model and supports offered to people addressing their nicotine addiction. It also outlines the concerns expressed by some submitters who are in favour of other models to regulate vaping in Australia.
- 2.4 Finally the chapter discusses the views on law enforcement and penalties issues, including the concerns over illicit trade and the growing black market and the definition of commercial possession in the civil penalty provisions of the bill.

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<sup>1</sup> See, for example, Australian Medical Association, *Submission 3*, [pp. 6–7]; Cancer Australia, *Submission 5*, [pp. 1–2]; VicHealth, *Submission 60*, pp. 1, 5–9; Kidsafe WA, *Submission 15*, p. 1; Professor Emily Banks et al, *Submission 62*, pp. 3–4; Australian Nursing & Midwifery Federation, *Submission 4*, [pp. 1–2].

<sup>2</sup> See, for example, Westcare, *Submission 19*, pp. 1–2; Collaboration for Evidence, Research, and Impact in Public Health (CERIPH), *Submission 14*, pp. 1–2; Injury Matters, *Submission 31*, [p. 1.].

<sup>3</sup> See, for example, Ms Fiona Patten, *Submission 165*, [pp. 1–3]; Mr Ryan Oakley, *Submission 152*, pp. 4–5; Mr Robert Richter KC, *Submission 91*, [p. 1]; Emeritus Professor Wayne Hall, *Submission 30*, pp. 1, 4–6.

## The final stage of the government's vaping reforms

- 2.5 The bill represents the final stage of the government's vaping reforms, following a series of regulation changes and reforms intended to address the issues of the illicit vaping market and its harms to the Australian community.<sup>4</sup>
- 2.6 The Department specified the work that has been undertaken to achieve effective tobacco control and vaping reform in Australia, including:
- implementation of Australia's National Tobacco Strategy 2023–2030;
  - establishment of a National E-Cigarette Working Group in February 2023;
  - establishment of the National Vaping Working Group in November 2023 to oversee the development and implementation of a National Vaping Enforcement Framework;
  - establishment of an Illicit Tobacco and E-Cigarette Commissioner within the Australian Border Force;<sup>5</sup>
  - banning importation of all disposable vapes from 1 January 2024; and
  - from 1 March 2024 banning importation of all vapes, limiting therapeutic vape flavours to mint, menthol and tobacco only and closing the Personal Importation Scheme for vapes.<sup>6</sup>
- 2.7 Many submitters to the inquiry expressed concerns about the harmful public health effects of vaping, both on individual health outcomes but also on population wide outcomes as a result of increased nicotine uptake.<sup>7</sup>

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<sup>4</sup> Department of Health and Aged Care, *Submission 1*, pp. 3–5.

<sup>5</sup> Department of Health and Aged Care, *Submission 1*, pp. 3–6.

<sup>6</sup> Department of Health and Aged Care, *Reforms to the regulation of vapes*, [Reforms to the regulation of vapes | Therapeutic Goods Administration \(TGA\)](#) (accessed 1 May 2024).

<sup>7</sup> See, for example, Department of Health and Aged Care, *Submission 1*, pp. 6–7; Professor Emily Banks et al, *Submission 62*, pp. 11–14; Australian Medical Association, *Submission 3*, [pp. 2–3]; Lung Foundation Australia, *Submission 8*, p. 5; VicHealth, *Submission 60*, pp. 6–7; Cancer Council Australia, *Submission 70*, [pp. 7–8]; Asthma Australia, *Submission 6*, [pp. 1–2]; VicHealth, *Submission 60*, pp. 6–8; National Heart Foundation of Australia, *Submission 65*, pp. 4–5; Thoracic Society of Australia and New Zealand, *Submission 61*, [pp. 2–3]; Cancer Council NSW, *Submission 71*, [p. 2]; A/Prof Stuart Thomas, *Submission 90*, [p. 2].

## The risk of a new generation becoming addicted to nicotine

- 2.8 The majority of submitters highlighted concerns about the increasing rates of vaping use amongst youth in Australia<sup>8</sup> and submitters agreed that the issue of high levels of youth vaping needed to be addressed by the government.<sup>9</sup>
- 2.9 Evidence presented to the committee indicates that the rate of youth vaping is continuing to rise.<sup>10</sup> Importantly, Associate Professor Michelle Jongenelis told the committee that young people are the most likely demographic to vape with the number of adolescents and young adults that currently vape increasing approximately five-fold since 2018/19.<sup>11</sup>
- 2.10 Cancer Australia emphasised to the committee the risk of non-smoking young people who vaped being three times more likely to take up smoking cigarettes in comparison to non-vapers, flagging that this represented an additional emerging risk in relation to the issue of youth vaping.<sup>12</sup> Moreover, young people who vape are likely to be doing so with a very high frequency:

Two-thirds to three-quarters of young people who have vaped started doing it before trying a conventional cigarette. About one-third children aged 12-17 who reported vaping at least once in last 30 days were using them daily or most days.<sup>13</sup>

- 2.11 Further, many submitters highlighted the unique health harms that can be caused when adolescents vape; including a range of mental health issues in addition to physiological and brain development issues.<sup>14</sup> Professor Emily Banks further elaborated on this issue by stating:

Young people are much more prone to addiction than older people. If you look at people who have a lifetime smoking habit, they will on average have started as teenagers. That's really because the brain is plastic at that time—you're laying down habits and you're laying down neural pathways. What

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<sup>8</sup> Westcare, *Submission 19*, [pp. 1–2]. See also: Dr Colin Mendelsohn, *Submission 21*, p. 5; TSG Franchise Management, *Submission 36*, [p. 5.]; Associate Professor Raglan Maddox, *Submission 56*, p. 7.

<sup>9</sup> See, for example, Professor Coral Gartner, *Submission 32*, [p. 1.]; Australian Council of State School Organisations, *Submission 13*, [p. 1]; National Centre for Youth Substance Use Research, *Submission 10*, pp. 3–6.

<sup>10</sup> See, for example, Associate Professor Michelle Jongenelis, *Submission 29*, p. 4; Associate Professor Raglan Maddox, *Submission 56*, p. 7; Professor Emily Banks, *Submission 62*, pp. 8–9; Associate Professor Becky Freeman, *Submission 59*, pp. 6–7; Australian Council of State School Organisations, *Submission 13*, [p. 6]; National Centre for Youth Substance Research, *Submission 10*, pp. 3–4.

<sup>11</sup> Associate Professor Michelle Jongenelis, *Submission 29*, p. 4.

<sup>12</sup> Cancer Australia, *Submission 5*, p. 3.

<sup>13</sup> Professor Emily Banks et al, *Submission 62*, p. 8.

<sup>14</sup> VicHealth, *Submission 60*, pp. 5–7. See also: Cancer Council Australia, *Submission 70*, [p. 9]; Stroke Foundation, *Submission 58*, p. 2.

we see with young people is that they can get readily addicted and then that can lead to a lifelong issue with addiction. We also see young people as particularly vulnerable to poisoning and toxicity via inhalation, particularly with young children.<sup>15</sup>

2.12 Evidence also indicates the vapes being used by children and young people are products that contain nicotine, even if they are marketed as non-nicotine or nicotine free products, with recent evidence from a study showing that 98 per cent of vapes confiscated from school students in NSW contained nicotine.<sup>16</sup>

2.13 Cancer Council Australia underscored the urgency of the situation by noting:

Use of vaping products is rising exponentially among young people. We have a rapidly closing window of opportunity to prevent a new generation of Australians from becoming addicted to nicotine.<sup>17</sup>

2.14 Of the issue of children being addicted to nicotine as a result of vaping, Mr Andy Mison of the Australian Secondary Principals' Association discussed the impacts:

In terms of how it manifests in kids behaviour, it's the same way that withdrawal symptoms from cigarettes would—agitation, irritation, irritability and a tendency to engage more readily in conflict cycles with other kids and with teachers. It distracts them, they're not focused on activity—healthy or otherwise. When challenged, it will often lead to what might be considered typical of an addict's response. It very quickly goes to a conflict cycle, which is not in the interest of the learner, the other kids in the environment or the teacher who's trying to get the job done.

It means a decrease of kids engaging in healthy physical activities because of the health impacts that smoking or nicotine and vaping is having on kids' lungs and respiratory systems. They're less inclined to get outside and be active and all those things that we know are really important for our young people. It's very concerning and it's not something we should be dealing with in schools.<sup>18</sup>

2.15 Mr Mark Brooke of the Lung Foundation of Australia further elaborated:

... e-cigarette use and vaping use have increased dramatically over recent years, particularly amongst young people and young adults. We are concerned and remain concerned for the future of those young people and the lung health of young adults. Whilst the long-term health impacts remain

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<sup>15</sup> Professor Emily Banks, private capacity, *Committee Hansard*, 1 May 2024, p. 42.

<sup>16</sup> Department of Health and Aged Care, *Submission 1*, p. 7.

<sup>17</sup> Cancer Council Australia, *Submission 70*, [p. 4].

<sup>18</sup> Mr Andy Mison, President, Australian Secondary Principals' Association, *Committee Hansard*, 2 May 2024, pp. 33–34.

unclear, one of the many recognised short-term impacts includes addiction to nicotine.<sup>19</sup>

### **Deliberate targeting of young people**

2.16 Submitters explained to the committee the specific tactics that are utilised to target young people in relation to vaping; including targeted advertisements, unregulated social media advertising and vaping products being sold in high adolescent traffic areas.<sup>20</sup>

2.17 The Australian Medical Association highlighted that:

Vaping companies spend most of their marketing budget on magazine and television advertising. Analysis showed that more than half of vaping adverts in the USA included features to appeal to youth, such as animation, content related to positive sensations, young actors, humour, promoting mood and individuality.<sup>21</sup>

2.18 Associate Professor Becky Freeman provided an illustrative example of what this marketing looks like in practice:

I was just on Instagram this morning and double-checked, and the influencer ad is still there. It's a young woman. She's putting on make-up. She's putting on a really fashionable outfit to go to a winter festival, and, at the very end of getting ready, she takes the BAT vape, puts it in a designer handbag and puts it over her shoulder, and she's all ready to go to the festival. To me, that is very clearly marketing to young people.<sup>22</sup>

2.19 Concerningly, researchers from the National Centre for Youth Substance Use Research found that 'even after accounting for vaping product use and established risk factors, exposure to vape advertisements at gas stations and on social media significantly correlated with lifetime, past 12-month, and past 30-day e-cigarette use among young individuals aged 12-18'.<sup>23</sup>

2.20 It was further explained to the committee that attitudinal shifts are occurring within the youth population that encourage vaping 'due to the widespread availability and promotion of vaping as a "safe" and "cool" alternative to smoking'.<sup>24</sup> Moreover, these effects continue to self replicate with a tendency

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<sup>19</sup> Mr Mark Brooke, Chief Executive Officer, Lung Foundation of Australia, *Committee Hansard*, 1 May 2024, p. 2.

<sup>20</sup> National Centre for Youth Substance Use Research, *Submission 10*, pp. 3–4. See also: Collaboration for Evidence, Research and Impact in Public Health, *Submission 14*, p. 1; Society of Hospital Pharmacists, *Submission 16*, [p. 1]; Professor Coral Gartner, *Submission 32*, [p. 1.]; Australian Council on Smoking and Health, *Submission 57*, p. 6; Associate Professor Becky Freeman, *Submission 59*, pp. 3–4; VicHealth, *Submission 60*, pp. 9–10; Associate Professor Emily Banks et al, *Submission 62*, p. 15.

<sup>21</sup> Australian Medical Association, *Submission 3*, p. 2.

<sup>22</sup> Associate Professor Becky Freeman, Private capacity, *Committee Hansard*, 1 May 2024, p. 48.

<sup>23</sup> National Centre for Youth Substance Use Research, *Submission 10*, pp. 3–4.

<sup>24</sup> VicHealth, *Submission 60*, p. 6.

towards tobacco use, with the Australian Council on Smoking and Health noting:

Adolescent susceptibility to smoking in 2022/23 is now equivalent to that of 2002, providing alarming evidence that the increase in vaping over the same time threatens to jeopardise tobacco control efforts to reduce smoking among young people.<sup>25</sup>

2.21 Some submitters further elaborated on the unique mechanisms through which young people are targeted by vapes; including disposable vapes disguised as toys, and other non-descript objects, as well as targeting individuals through flavours designed to replicate lollies or sweet flavours.<sup>26</sup>

2.22 Associate Professor Becky Freeman underlined the importance of this legislation to stop the targeting of young Australians:

We also know from the Gen Vape study that young people find it incredibly easy at the moment to get their hands on a vape. They can literally go into any shop, any store and purchase one themselves. We need this legislation to end that easy access. A 14-year-old on their way home from school shouldn't be able to pop into a shop where they would buy lollies, ice cream or chocolate and also pick up a vape at the same time. This legislation that has been proposed closes down that non-nicotine loophole that has been exploited by retailers who, in broad daylight, sell illicit, highly addictive products to young kids.<sup>27</sup>

2.23 Further, Asthma Australia emphasised the importance of the bill and its advertising restrictions. It discussed that the bill:

... will help to stop the advertising of e-cigarettes and reduce their appeal in terms of flavours, colours and packaging. These are important measures to reduce the appeal of e-cigarettes to children and young people and urgently needed.<sup>28</sup>

2.24 The Department specified the intent of the legislation to deliberately address the issues of widespread vaping use amongst children and young people. In acknowledging the impact of widespread marketing and targeted advertisements directed at young people, as well as the use of colours and flavours to draw in young people, the Department highlighted that 'the reforms are intended to reduce rates of vaping and smoking, and prevent long term adverse effects on population health, particularly among youth and young adults'.<sup>29</sup>

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<sup>25</sup> Australian Council on Smoking and Health, *Submission 57*, p. 5.

<sup>26</sup> Associate Professor Becky Freeman, *Submission 9*, p. 4. See also: VicHealth, *Submission 60*, p.11; National Heart Foundation of Australia, *Submission 65*, p. 2.

<sup>27</sup> Associate Professor Becky Freeman, Private capacity, *Committee Hansard*, 1 May 2024, p. 42.

<sup>28</sup> Asthma Australia, *Submission 6*, [p. 2].

<sup>29</sup> Department of Health and Aged Care, *Submission 1*, p. 7.

2.25 Furthermore, Professor Anthony Lawler of the Department also highlighted that the bill:

... acknowledges and addresses the risk that wide availability of vaping products presents to public health, particularly for children and young Australians. Strengthened approaches to compliance will prevent vapes from being readily and effectively marketed and available to young people.<sup>30</sup>

2.26 In addition to the legislative reforms outlined in the bill, the Minister has partnered with Australian state and territory Health and Education Ministers to write to school principals, raising awareness of the reforms and resources available to support schools, students and their families to address vaping.<sup>31</sup>

### **The impact on Aboriginal and Torres Strait Islander peoples**

2.27 Participants in the inquiry highlighted the unique impact of vaping and smoking on Aboriginal and Torres Strait Islander communities.

2.28 Associate Professor Raglan Maddox emphasised that Aboriginal and Torres Strait Islander people and communities are 'disproportionately harmed' by tobacco use and have historically been targeted by the tobacco industry; a trend which is now continuing with the proliferation of vapes through Indigenous communities.<sup>32</sup>

2.29 As highlighted by Professor Tom Calma there has been a significant increase in vaping in First Nations communities over recent years:

One of the simplest answers is that we've got about 250 staff, located across the nation, who work on adapting an Indigenous smoking program. I brought in quite a significant number of them from remote communities in 2022. There was very good evidence of vaping in remote Australia. We reconvened in 2023 and it was rife. It was everywhere. Prior to our reaching remote communities, there was evidence of people vaping in urban environments and regional environments, but it hadn't really progressed. The big question was: how did it enter the communities so fast? It was really the illicit sale, and that was done not by Aboriginal and Torres Strait Islander people but by contractors coming into the community, as well as some organised groups, who were making it available.<sup>33</sup>

2.30 Associate Professor Raglan Maddox further discussed the prevalence of vaping in Aboriginal and Torres Strait Islander communities, highlighting early findings of his research:

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<sup>30</sup> Professor Anthony Lawler, Deputy Secretary, Health Products Regulation Group, Department of Health and Aged Care, *Committee Hansard*, 2 May 2024, p. 47.

<sup>31</sup> Department of Health and Aged Care, *Submission 1*, p. 10.

<sup>32</sup> Associate Professor Raglan Maddox, *Submission 56*, pp. 5–6.

<sup>33</sup> Professor Tom Calma, Private capacity, *Committee Hansard*, 1 May 2024, p. 35.

We have had focus groups and interviews with many, many communities that raise concerns about vaping, regardless of whether we are there to talk about vaping. The conversations have been around the pervasive nature and the ability for industries to manipulate and target children in particular—but not just children—under the false pretence that this is a nonaddictive product, a healthier product or a safer product. Unfortunately, we've had many interviews where young people have thought that by taking up this product it might not be addictive. Then, as they process, they realise that they've been vaping in bed, and waking up to vape, sleeping with the vape under their pillow, showering with their vape and other things, and that they might be addicted.<sup>34</sup>

- 2.31 To support the proposed legislation, the government is providing an additional \$141.2 million for the Tackling Indigenous Smoking program.<sup>35</sup> As described by Cancer Australia, the Tackling Indigenous Smoking program is:

... an Indigenous-led program offering locally tailored tobacco control activities in communities, led by 37 regional teams. Local activity is supported by mass-media campaigns, individual cessation advice provided by Aboriginal and Community Controlled Health Organisations and via Quitline. Independent evaluation of TIS has demonstrated positive impact on attitudes towards being smoke-free, smoking less, and intention to quit in areas serviced by TIS teams.<sup>36</sup>

### **A legislative model that closes the loopholes**

- 2.32 A number of submitters supported the legislation, noting that it would close the legal loophole 'whereby non-nicotine vaping products are exempt from the prescription-only model'.<sup>37</sup>
- 2.33 Mr Scott Phillips from Kidsafe Western Australia told the committee that the bill 'will put an end to the youth vaping epidemic by closing loopholes and boosting enforcement while observing access to therapeutic vapes for those trying to quit smoking'.<sup>38</sup>
- 2.34 Some submitters highlighted the dangers of this loophole noting that vapes that are advertised as 'non-nicotine' often contain nicotine and are subject to weaker regulation and enforcement.<sup>39</sup> Associate Professor Raglan Maddox discussed the issue of illegal vaping and the associated risks of addiction:

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<sup>34</sup> Associate Professor Raglan Maddox, Private capacity, *Committee Hansard*, 1 May 2024, p. 36.

<sup>35</sup> Department of Health and Aged Care, *Submission 1*, p. 11.

<sup>36</sup> Cancer Australia, *Submission 5*, p. 3.

<sup>37</sup> Australian Council on Smoking and Health, *Submission 57*, p. 6. See also: VicHealth, *Submission 60*, p. 9; Cancer Council Australia, *Submission 70*, [p. 18].

<sup>38</sup> Mr Scott Phillips, Chief Executive Officer, Kidsafe Western Australia, *Committee Hansard*, 2 May 2024, p. 2.

<sup>39</sup> Associate Professor Becky Freeman, *Submission 59*, pp. 6–7. See also: VicHealth, *Submission 60*, p. 9.



Most people who vape accessed nicotine e-cigarettes without a prescription (87%) despite being illegal to do so. Further, almost one third of people who vape, had tried to quit vaping in the past but have been unsuccessful.<sup>40</sup>

2.35 As highlighted earlier in this chapter, evidence received by the committee shows that young people are developing nicotine addictions, not knowing their vapes contain nicotine and that this is having significant impacts on their mental and physical health and wellbeing.

2.36 The Australian Council on Smoking and Health highlighted the difficulties this creates in terms of enforcement:

The fact that non-nicotine vapes may legally be sold makes it much more expensive and difficult for authorities to target shipments for inspection, to seize products for testing and to secure prosecutions for illegal import, storage and sale of nicotine vaping products.<sup>41</sup>

2.37 Some submitters emphasised that the current legislative environment means that adult smokers already require a prescription to legally access nicotine vaping products and this will remain unchanged in this legislation.<sup>42</sup> However, as stated by Associate Professor Becky Freeman, the difference lies in the fact that:

... the proposed laws will actually make enforcement possible, as retailers, both bricks-and-mortar and online, will no longer be able to openly and easily sell illicit products under the guise that the vapes they are selling are supposedly “non-nicotine.” Implementing the prescription model as intended requires effective enforcement tools – this Bill is that tool.<sup>43</sup>

2.38 Participants in the inquiry expressed concerns about the inability to pursue appropriate enforcement of illicit activities on the basis of the current legal loopholes.<sup>44</sup> Some submitters supported the proposed reforms given they established clear and indisputable powers for enforcement agencies to start to address illicit vaping activities that occurred outside of the prescription model.<sup>45</sup> As the Lung Foundation of Australia emphasised:

The proposed reforms allow for appropriate and effective enforcement by States and Territories. As all e-cigarette products and devices will only be able to be purchased through an Australian pharmacy with a prescription,

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<sup>40</sup> Associate Professor Raglan Maddox, *Submission 56*, p. 6.

<sup>41</sup> Australian Council on Smoking and Health, *Submission 57*, p. 6.

<sup>42</sup> Associate Professor Raglan Maddox, *Submission 56*, p. 6. See also: Mr Richard Lee, Chief Executive Officer of Liber Pharmaceutical, *Committee Hansard*, 1 May, p. 27.

<sup>43</sup> Associate Professor Becky Freeman, *Submission 59*, pp. 6–7.

<sup>44</sup> Australian Medical Association, *Submission 3*, pp. 3–6. See also: National Heart Foundation of Australia, *Submission 65*, p. 3.

<sup>45</sup> Australian Medical Association, *Submission 3*, pp. 3–6. See also: Kidsafe WA, *Submission 15*, [p. 1], Injury Matters, *Submission 31*, [p. 1].

the enforcement of retailers selling any e-cigarette product or device outside of this model will be more easily and effectively enforceable.<sup>46</sup>

- 2.39 Furthermore, the Australian Council on Smoking and Health argued that this model will assist in reforming the widespread issues with illicit vapes currently seen in Australia:

While utilisation of the existing prescription model for vapes has been relatively low, the “free for all” market has negated the need to use it. The Bill will resolve problems with the existing legal framework that have rendered border enforcement all but unfeasible and will facilitate patients seeking prescriptions from a medical practitioner, who will be equipped to support them.<sup>47</sup>

- 2.40 Cancer Council Australia emphasised why this would be preferred in contrast to a regulatory sales model:

Regulating sale of vaping products by retailers would not guarantee compliance with laws and would require a huge enforcement effort at the local level. Restricting importation and sale of vaping products to the pharmaceutical supply chain by contrast will significantly reduce the number of players in the field and consequently the cost of compliance monitoring and will make illegal sales much more visible.<sup>48</sup>

- 2.41 Mr Richard Lee of Liber Pharmaceuticals discussed the consequences of failing to pass the legislation:

Failure to pass these regulations will ensure that enforcement agencies aren't equipped to address the rise of the illicit market, and it's a matter of time before the efforts to stop illegal imports are simply bypassed.<sup>49</sup>

- 2.42 Of the enhanced enforcement mechanisms specified within the bill, the Department noted:

The provisions in the Bill build on global evidence on tobacco control, which demonstrates that reducing the social acceptability of e-cigarettes, ensuring effective and comprehensive governance arrangements and regulatory settings across the supply chain, and addressing the availability of informal distribution networks are critical to reducing the illicit supply of vapes.<sup>50</sup>

- 2.43 Moreover, the Australian Border Force specified its support of the provisions of the bill, noting that:

... the ability to seize and immediately destroy vaping goods would significantly enhance the ABF's ability to effectively deal with imported

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<sup>46</sup> Lung Foundation of Australia, *Submission 8*, p. 10.

<sup>47</sup> Australian Council on Smoking and Health, *Submission 57*, p. 6.

<sup>48</sup> Cancer Council Australia, *Submission 70*, [p. 17].

<sup>49</sup> Mr Richard Lee, Chief Executive Officer at Liber Pharmaceuticals, *Committee Hansard*, 1 May 2024, p. 28.

<sup>50</sup> Department of Health and Aged Care, *Submission 1*, p. 9.

vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.<sup>51</sup>

### Support for the proposed model

- 2.44 A number of submitters emphasised that Australia has a history of world-leading tobacco reforms, that have subsequently been replicated in other countries, such as plain package reforms for cigarettes and noted that the proposed reforms continue this trend.<sup>52</sup>
- 2.45 In relation to the proposed model outlined in the bill, the committee received feedback in support of the legislation, noting that it balanced enabling access to vapes as a therapeutic device, while also facilitating the implementation of enforcement mechanisms to stop the provision of illicit vapes to children.
- 2.46 As the Department outlined, the purpose of the legislation is to support:
- ... legitimate patient access to therapeutic vapes, while restricting the importation, domestic manufacture, supply, commercial possession and advertisement of disposable single use and non-therapeutic vapes.<sup>53</sup>
- 2.47 As the Cancer Council of Australia outlined, the reforms proposed in the bill are:
- ... not just about keeping vaping products out of the hands of children; it is also about controlling the sale and supply of a product that—while having some potential clinical benefit—also contains a highly addictive substance. Continuing to regulate nicotine vapes as prescription-only products is the only feasible means of preventing nicotine addiction among people who are over the age of 18.<sup>54</sup>
- 2.48 Furthermore, the Lung Foundation of Australia emphasised the importance of the reforms as seeking to regulate vaping devices for their intended use: smoking cessation. The Lung Foundation of Australia stated that the:
- ... prescription pathway takes them out of the hands of young people and non-smokers while still allowing for people who are trying to quit smoking to access them under medical supervision.<sup>55</sup>
- 2.49 Further, the Asthma and Respiratory Foundation of New Zealand ‘strongly supports the prescription-only regulation of vaping products in Australia and

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<sup>51</sup> Department of Home Affairs, *Submission 2*, p. 4.

<sup>52</sup> Australian Nursing and Midwifery Federation, *Submission 4*, p. 4. See also: Australian Council on Smoking and Health, *Submission 57*, p. 7; Thoracic Society of Australia and New Zealand, *Submission 61*, [p. 2]; Professors Chapman, Daube and Peters, *Submission 208*, p. 5.

<sup>53</sup> Department of Health and Aged Care, *Submission 1*, p. 7.

<sup>54</sup> Cancer Council Australia, *Submission 70*, [p. 13].

<sup>55</sup> Lung Foundation Australia, *Submission 8*, p. 8.

strongly recommends the Committee endorse the proposals included in the legislation in order to avoid a similar situation to that of New Zealand'.<sup>56</sup>

2.50 Mr Richard Lee, of Liber Pharmaceuticals, explained the importance of effective safety evaluation of the products to be covered under the proposed legislation:

In 2020 the TGA designated vaping products a schedule 4 medicine after a thorough risk-benefit analysis. This is how all pharmacologically active manufactured ingredients are made available in Australia. We see it as absurd to suggest that only one product—nicotine—should be treated differently from all others, including other forms of nicotine replacement therapy.<sup>57</sup>

### **Vaping as a smoking cessation tool**

2.51 The committee heard of the original intended purpose of vapes as a smoking cessation aid. A number of participants in the inquiry shared their individual stories about quitting smoking after starting vaping.<sup>58</sup> An example of the benefits of vapes as a smoking cessation tool was provided by Mr Christopher Franzi of Shoozitech:

In 2011, after 14 years of cigarette usage, I transitioned to vaping and have not smoked since. My health improvements were significant: enhanced fitness, better sleep quality, weight loss, and cessation of snoring.<sup>59</sup>

### ***Concerns about the unknown effects as a smoking cessation tool***

2.52 While acknowledging the success some individuals have had using vaping as a smoking cessation tool, it is important to recognise that there are a range of therapeutic smoking cessation treatments, including nicotine gum or patches, which are available and come more highly recommended for the purposes of smoking cessation.<sup>60</sup> Current recommendations by the Royal Australian College of General Practitioners describe e-cigarettes as a 'late- or last-line therapy for smoking cessation'.<sup>61</sup>

2.53 As emphasised by Dr Michael Bonning of the Australian Medical Association:

<sup>56</sup> Asthma and Respiratory Foundation of New Zealand, *Submission 104*, [p. 1].

<sup>57</sup> Mr Richard Lee, Chief Executive Officer at Liber Pharmaceuticals, *Committee Hansard*, 1 May 2024, pp. 27–28.

<sup>58</sup> See, for example, Mr Justin Leary, *Submission 109*, [pp. 1–2]; Ms Diane Iveson, *Submission 119*, [pp. 1–2]; Ms Cat Wright, *Submission 137*, [pp. 1–2]; The Vape Store, *Submission 108*, [pp. 6–14]; Mr Robert Richter KC, *Submission 91*, [pp. 1–2]; Mr Shaun Goodwin, *Submission 176*, [p. 1.]; Ms Lauren Fisher, *Submission 184*, [p. 1.]; Mr Jack Langdon, *Submission 199*, [p. 1].

<sup>59</sup> Shoozitech, *Submission 38*, [p. 1].

<sup>60</sup> Australian Medical Association, *Submission 3*, p. 2. See also: Professor Emily Banks et al, *Submission 62*, p. 10.

<sup>61</sup> Associate Professor Emily Banks et al, *Submission 62*, p. 15.

... as a prescriber, I would think of this as a fourth-line intervention in terms of how I would interact with people who want to undertake a nicotine cessation pathway from either smoking or vaping. Like many things, it's about risks and benefits. I would use less-risky, known efficacious products first. Then I would consider vapes—a regulated, medicated vape.<sup>62</sup>

- 2.54 Moreover, it was highlighted that in order for vapes to be considered as an effective smoking cessation aid, they must be utilised in partnership with healthcare professionals and accompanied by behavioural support.<sup>63</sup>
- 2.55 Professors Chapman, Daube and Peters specified the importance of differentiation between these existing forms of nicotine replacement therapy (NRT) and the prevalence of nicotine vaping products (NVPs) across the market:

There is zero evidence of children or adult non-smokers sharing NRT gum or comparing NRT patches as a “lifestyle choice”. The pernicious difference between NVPs and NRT is that NVPs are flavoured, often come in luridly coloured apparatus and can deliver high, rapidly addictive nicotine dose. These differences are critical in explaining why NRT is today available in supermarkets but NVPs are to be prescribed.<sup>64</sup>

- 2.56 Further, submitters supported the intent of the legislation to treat vapes as a therapeutic device, to be provided under the supervision of a medical professional.<sup>65</sup> Cancer Council Australia highlighted:

Australia’s prescription access model does not ‘ban’ the use of vaping products, but it can and should prevent those with commercial interests from profiting from and promoting addictive patterns of use. The prescription access model ensures vaping products are used only after consultation with a health practitioner that can empower individuals to make informed choices about their health based on full information.<sup>66</sup>

### ***Additional supports for accessing smoking cessation under the new model***

- 2.57 In regards to the requirements for Australian adults to access a prescription in order to access vapes as pharmaceutical products, it was highlighted that:

The Government has also introduced streamlined access arrangements that make it quicker and easier for GPs and Nurse Practitioners to prescribe. The

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<sup>62</sup> Dr Michael Bonning, Chair of the Public Health Committee, Australian Medical Association, *Committee Hansard*, 1 May 2024, p. 23.

<sup>63</sup> Thoracic Society of Australia and New Zealand, *Submission 61*, [p. 3].

<sup>64</sup> Professors Chapman, Daube and Peters, *Submission 208*, p. 7.

<sup>65</sup> Cancer Council Australia, *Submission 70*, [p. 12]. See also: Lung Foundation Australia, *Submission 8*, p. 8; Collaboration for Evidence, Research, and Impact in Public Health (CERIPH), *Submission 14*, p. 2.

<sup>66</sup> VicHealth, *Submission 60*, p. 13.

Australian Medical Association has stated that it is confident that doctors will be able to meet demand.<sup>67</sup>

2.58 Furthermore, Dr Michael Bonning of the Australian Medical Association noted:

If we look historically, GPs have managed smoking cessation and vaping cessation over a long period of time. They've managed smoking cessation for decades now. It's a normal part of what we do. That is modelling 900,000 extra consults against about 180 million, so it's a very small increase. It is, however, a very important increase and needs to be supported and managed well, because GPs are the front line of this interaction. These will not be just singular interactions; they will be a course of engagement with patients. But it is something that is well within the hands of GPs out in the community, and certainly we are seeing good outcomes from a behavioural and motivational interviewing model, which we are taught through our training but which we also, I think, use on a regular basis for many addictive products.<sup>68</sup>

2.59 The Department further emphasised that the proposed model within the legislation will offer appropriate opportunities for smoking cessation support:

Ensuring that vapes are only accessed with medical supervision via pharmacies provides an opportunity for users to receive appropriate advice from a health professional on the risks associated with their use and other tailored health advice.<sup>69</sup>

2.60 Recognising the potential of vapes as a smoking cessation device, the Department emphasised that the intent of the legislation is to effectively treat them as such:

As vapes have been marketed and used in Australia for the therapeutic purpose of smoking cessation, it is appropriate that they are subject to the same regulatory controls as any other therapeutic goods.<sup>70</sup>

### ***Further support for smoking cessation and public education***

2.61 The Department further specified that this legislation will be supported by broader actions for education and communication related to the reforms and how individuals will be impacted.

2.62 The Department is:

- supporting health practitioner education on the regulatory reforms, codesigned with health practitioners and delivered by the TGA, RACGP and the Pharmaceutical Society of Australia;

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<sup>67</sup> Cancer Council Australia, *Submission 70*, [p. 19].

<sup>68</sup> Dr Michael Bonning, Chair of the Public Health Committee, Australian Medical Association, *Committee Hansard*, 1 May 2024, p. 22.

<sup>69</sup> Department of Health and Aged Care, *Submission 1*, p. 11.

<sup>70</sup> Department of Health and Aged Care, *Submission 1*, p. 4.

- developing webinars for national health investigators, policing authorities and prosecutors about the proposed reforms;
  - supporting the Minister to communicate with school Principals to raise awareness of the reforms and resources available to support schools, students and their families to address vaping.<sup>71</sup>
- 2.63 Some submitters to the inquiry also stressed the importance of a comprehensive public health education campaign to ‘equip teachers, families, parents, carers and children with evidence-based information about the dangers of vaping’.<sup>72</sup>
- 2.64 For example, inquiry participants emphasised the need to develop resources for schools, teachers and parents.<sup>73</sup> At a hearing, Mr Damien Ellwood, President of the Australian Council of State Schools Organisations said supports needed would include:
- Properly targeted, well-rounded information to teachers, principals, school-leaders and families. Our survey indicated that most families are concerned about the health effects of vaping. The parents and carers have indicated that they are seeking the information from a whole range of sources but they are not confident about talking to young people about the risks and the issues around vaping. So they really need that information and it needs to be targeted.
- For teens, they probably need first-person examples of where things have gone wrong with vaping—the health effects that are coming forward—so that they can relate to someone of their age and the impacts it's having on them.<sup>74</sup>
- 2.65 Associate Professor Raglan Maddox further highlighted the existing opportunities for further nicotine cessation support:
- ... to increase resourcing, including training and funding to improve referral pathways to tobacco and nicotine cessation supports, and capability and capacity building to ensure the health workforce can provide effective evidence-based nicotine cessation supports.<sup>75</sup>

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<sup>71</sup> Department of Health and Aged Care, *Submission 1*, pp. 9–10.

<sup>72</sup> Australian Council of State School Organisations, *Submission 13*, [p. 3]. See also: VicHealth, *Submission 60*, pp. 14–15.

<sup>73</sup> See, for example: Mrs Dianne Giblin, Chief Executive Officer, Australian Council of State School Organisations, *Committee Hansard*, p. 3; Mr Scott Phillips, Chief Executive Officer, Kidsafe Western Australia, *Committee Hansard*, 2 May 2024, p. 3; Mrs Jennifer Branch-Allen, President, Australian Parents Council, *Committee Hansard*, 2 May 2024, p. 4.

<sup>74</sup> Mr Damien Ellwood, President, Australian Council of State School Organisations, *Committee Hansard*, 2 May 2024, p. 8.

<sup>75</sup> Associate Professor Raglan Maddox, *Submission 56*, p. 10.

2.66 The need for enhanced support for smoking cessation services targeted towards those who are most significantly affected by vaping was emphasised.<sup>76</sup> VicHealth discussed the importance of this holistic approach:

Legislation is of critical importance, but it must happen in tandem with support for people who wish to quit nicotine and prevention efforts with young people, including in schools. ... Targeted cessation support services will be crucial for young people addicted to nicotine alongside the declining availability of harmful, non-therapeutic vapes if these reforms are passed.<sup>77</sup>

2.67 Professors Chapman, Daube and Peters commended that the measures in the bill 'are not being implemented in isolation, but as part of a comprehensive approach that seeks to reducing smoking and its harms'. Particularly the bill would:

... ensure effective controls on access to and marketing of e-cigarettes and an ever-increasing range of further novel products that will attract children and young people to a new range of addictive products. We also note that the Government has made a commitment to substantially increase funding for enforcement and public education, and that this approach has been supported by all states and territories.<sup>78</sup>

2.68 The Department reiterated its commitment to this approach by outlining the specific measures aimed at expanding smoking and vaping cessation support and funding for public health campaigns aimed at addressing tobacco and vaping. These will include:

- a national campaign to target young people, their parents, carers and communities, as well as a stream of activities dedicated to reaching teachers and the education sector;
- a national campaign to target adults, with a focus on priority and at-risk population groups;
- a national online cessation hub that contains information, tools, resources and a system to direct consumers to the best support mechanisms to assist them quit smoking and vaping;
- redevelopment of the My QuitBuddy app to support smoking and vaping cessation;
- clinical guidance updates to support the health workforce, developed and delivered by relevant health professional bodies such as the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia;
- improved access to Quitline services across the country; and

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<sup>76</sup> VicHealth, *Submission 60*, pp. 14–15.

<sup>77</sup> VicHealth, *Submission 60*, pp. 14–15.

<sup>78</sup> Professors Chapman, Daube and Peters, *Submission 208*, pp. 4–5.



- the expansion of the Tackling Indigenous Smoking Program.<sup>79</sup>

### **Recommendations for an alternative approach**

2.69 While submitters differed in their perspectives for the best mechanism for reform, participants in the inquiry tended to agree that there was a need for reform to the current system.<sup>80</sup> As effectively summarised by the Alcohol and Drug Foundation:

Australia's current approach to the regulation of vaping products has been unsuccessful to date. The supply of unregulated vaping products in retail outlets is of significant concern, as a large majority have been found to contain nicotine, and sellers are operating with effective impunity.<sup>81</sup>

2.70 Submitters recommended a range of alternative options to the proposed approach outlined in the bill, including regulatory models.

### **Regulation similar to alcohol and tobacco**

2.71 Some submitters recommended a legislated model similar to alcohol and cigarettes, which would include regulation of vaping sales to adults only through licenced vaping outlets, with strong controls on imports, advertising and packaging and labelling requirements.<sup>82</sup> Under a model such as this, the potential benefits of taxing vaping products for government revenue were also highlighted.<sup>83</sup> Additionally, some submitters argued that such a model would work better compared to the proposed model, arguing the proposed model would operate as a prohibition model and be unlikely to succeed.<sup>84</sup>

### ***Proposed models – the United Kingdom and New Zealand***

2.72 A number of submitters sought to discuss the international case studies of New Zealand and the United Kingdom.

2.73 In New Zealand, a regulatory model has been pursued, including a minimum age of purchase, a licencing model and requirements for products needing to be

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<sup>79</sup> Department of Health and Aged Care, *Submission 1*, p. 11.

<sup>80</sup> See, for example, Emeritus Professor Wayne Hall AM, *Submission 30*; 360Edge, *Submission 9*; Kidsafe WA, *Submission 15*.

<sup>81</sup> Alcohol and Drug Foundation, *Submission 7*, p. 1.

<sup>82</sup> Dr Alex Wodak, *Submission 33*, [p. 5]. See also: Mr Rohan Pike, *Submission 24*, p. 5; Dr James Martin, *Submission 25*, [p. 4]; Mr Robert Richter KC, *Submission 91*, [p. 2].

<sup>83</sup> Dr Ron Borland, *Submission 27*, p. 3.

<sup>84</sup> Dr Alex Wodak, *Submission 33*, [p. 8]. See also: Emeritus Professor Ian Webster, *Submission 34*, p. 1, Hon Dr Brain Walker MLC, *Submission 35*, p. 1; TSG Franchise Management, *Submission 36*, [p. 5]; Australian Association of Convenience Stores, *Submission 78*, [p. 1]; Dr Robert Graham, *Submission 28*, [p. 1].

compliant with labelling, product quality and nicotine concentration limits.<sup>85</sup> There are also restrictions on flavours and colours. However, there are continuing concerns in New Zealand about the widespread availability of vapes, vaping in schools and educational institutions and calls for greater enforcement powers.<sup>86</sup>

- 2.74 Comparatively, the United Kingdom specifies vapes as adult consumer products that can be sold from unlicensed retail stores and online.<sup>87</sup> A minimum age of sale is specified, as well as particular labelling and health warning requirements and limits on nicotine concentration.<sup>88</sup>

#### *Concerns with international models*

- 2.75 However, some submitters maintained the need for caution in evaluating the example of the United Kingdom:

Whilst the approach taken in the UK was originally backed by some health organisations, many public health experts have subsequently acknowledged that the UK's initial approach "has backfired" resulting in a significant increase in children vaping, providing clear evidence that a minimum purchase age is not adequate protection. These concerns are reflected in the general population, as the majority of UK adults— across the political spectrum—now support measures to enhance vaping regulation, such as banning bright colours and names of sweets on vapes, and banning the promotion of vapes at point of sale.<sup>89</sup>

- 2.76 For example, following Australia's lead in banning disposable vapes, a number of other countries have enacted similar reforms recently:

Numerous other countries are increasingly announcing and implementing strict controls to prohibit or restrict the supply, availability and promotion of e-cigarettes in view of their public health harms. For instance, New Zealand, the United Kingdom, France, Belgium and Scotland have recently announced plans to prohibit the supply of disposable single use vapes.<sup>90</sup>

- 2.77 Dr Sandro Demaio of VicHealth emphasised the importance of caution in relation to following the lead of international countries:

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<sup>85</sup> Dr Colin Mendelsohn, *Submission 21*, p. 19. See also: Action for Smokefree Aotearoa New Zealand, *Submission 106*, pp. 3–5; Emeritus Professor Robert Beaglehole, *Submission 83*, p. 1; Associate Professor George Laking MD PhD FRACP, *Submission 92*, p. 2; From the Fields Pharmaceutical, *Submission 95*, p. 14; Professor Matthew Rimmer, *Submission 98*, pp. 172–177; Professor Ognjen Brborovic, *Submission 99*, [p. 1].

<sup>86</sup> Dr Matthew Rimmer, *Submission 98*, pp. 173–176.

<sup>87</sup> Dr Colin Mendelsohn, *Submission 21*, p. 23.

<sup>88</sup> Dr Colin Mendelsohn, *Submission 21*, p. 23. See also: World Vapers' Alliance, *Submission 107*, [p. 3], Dr Arifin Fii, *Submission 82*, [p. 3]; Professor Matthew Rimmer, *Submission 98*, pp. 163–172.

<sup>89</sup> Australian Council on Smoking and Health, *Submission 57*, p. 7.

<sup>90</sup> Department of Health and Aged Care, *Submission 1*, p. 4.

This is a global challenge and countries which have regulated vapes with a non-prescription approach—such as the UK and New Zealand—are now seeing some of the highest rates of youth vaping in the world. In fact, New Zealand has the second highest rates of youth vaping in the OECD. This is not a path we want to follow.<sup>91</sup>

2.78 The Asthma and Respiratory Foundation of New Zealand noted:

Under our retail model, there are currently more than 1500 Specialist Vape Retailers (SVRs) registered in New Zealand - more than four times the number of KFC and McDonalds stores combined, and this does not take into account the 4000 convenience stores and service stations.

Overall, Kiwis are the world's second biggest vapers, behind Estonia, according to the OECD's 2023 global health snapshot despite new regulations implemented by the Government to curb the vaping epidemic.<sup>92</sup>

2.79 Moreover, Professor Emily Banks provided further perspective on the issue of international examples:

I can also add that 34 countries do not allow the consumer sales of nicotine vaping products—and that covers 41 per cent of the world's population—and a further 25 per cent have very strict regulations. For example, China is only allowing tobacco flavour for its own internal markets. We often hear it stated that Australia is in an outlier position, but in fact it's kind of in the middle. There are large portions of the world where e-cigarettes are not legal as consumer products. We do tend to see lower youth use in the countries where it's not available as a consumer product.<sup>93</sup>

### **Proposed pharmacy only model**

2.80 Comparatively, other submitters emphasised the potential associated with a pharmacy only model, which would see vapes sold in pharmacies by pharmacists only, similar to nicotine gum, patches and inhalers.<sup>94</sup> Emeritus Professor Wayne Hall noted that this model would remove the barrier of accessing a doctor's prescription, while also maintaining the ability for individuals to access vapes as a therapeutic smoking cessation device under supervision.<sup>95</sup>

2.81 A few submitters highlighted that some doctors are concerned about prescribing nicotine liquid or vaping devices as smoking cessation tools and that eliminating

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<sup>91</sup> Dr Sandro Demaio, Chief Executive Officer at VicHealth, *Committee Hansard*, 1 May 2024, p. 39.

<sup>92</sup> Asthma and Respiratory Foundation of New Zealand, *Submission 104*, [p. 1].

<sup>93</sup> Professor Emily Banks, Private capacity, *Committee Hansard*, 1 May 2024, p. 43.

<sup>94</sup> Emeritus Professor Wayne Hall, *Submission 30*, p. 6; See also: Professor Ron Borland, *Submission 27*, p. 3.

<sup>95</sup> Emeritus Professor Wayne Hall, *Submission 30*, p. 6.

a doctor's prescription may be a useful consideration in relation to the proposed legislation.<sup>96</sup>

### **Support for a harm reduction approach**

2.82 The Queensland Network of Alcohol and Other Drug Agencies emphasised the importance of regulation as a mechanism to ensure safety and quality:

Many of the documented harms from vaping use are associated with a poorly regulated market, and a lack of quality testing, with evidence showing that risks increase:

- when products have a high nicotine concentration or greater volume
- where e-liquids have been adulterated or are an 'at-home' preparation
- if products are inadequately labelled or child-resistant packaging is not used
- with the promotion and marketing of some products, including with flavourings
- in situations where products have been personally imported.<sup>97</sup>

2.83 The Alcohol and Drug Foundation further spoke to these issues of regulation and safety, highlighting support for an approach that:

... balances the accessibility of nicotine vaping products for individuals wishing to access them, while ensuring that access is appropriately limited to minimise harm in the community.<sup>98</sup>

2.84 A number of submitters also emphasised the importance of a consistent approach to drug regulation being applied to vaping, in line with the broader approach taken in the National Drug Strategy 2017–2026.<sup>99</sup> Particularly, submitters recommended a harm minimisation approach being taken where people are supported to access vaping products as a mechanism to avoid use of cigarettes as the more harmful tobacco products.<sup>100</sup>

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<sup>96</sup> Dr Colin Mendelsohn, *Submission 21*, p. 6. See also: Emeritus Professor Wayne Hall, *Submission 30*, p. 6.

<sup>97</sup> Queensland Network of Alcohol and Other Drug Agencies, *Submission 11*, p. 3.

<sup>98</sup> Alcohol and Drug Foundation, *Submission 7*, p. 3.

<sup>99</sup> Dr James Martin, *Submission 25*, [p. 4]. See also: Dr Alex Wodak, *Submission 33*, [p. 7]; Emeritus Professor Ian Webster, *Submission 34*, p. 1; Dr Ingrid van Beek and Professor Lisa Maher, *Submission 23*, pp. 1–3.

<sup>100</sup> Dr Ingrid van Beek and Professor Lisa Maher, *Submission 23*, pp. 1–3. See also: Australian Alcohol and other Drugs Council, *Submission 20*, [p. 1]; Alcohol and Drug Foundation, *Submission 7*, p. 1.

### *The need for safety and chemical regulation*

2.85 A number of submitters expressed concern about the specific types of chemicals identified within vapes.<sup>101</sup> As the Lung Foundation of Australia emphasised, toxic chemicals found in e-cigarettes include:

- heavy metals such as nickel and silicon;
- volatile organic compounds such as benzene, which is found in car exhaust and can be toxic at sufficient doses;
- cancer-causing chemicals such as acetaldehyde, acrolein, and formaldehyde which are known to cause lung and heart disease;
- phthalates which are used to make plastics, many have reproductive toxicity, and can be endocrine disrupting; and
- pesticides.<sup>102</sup>

2.86 It was also additionally noted the harms that can be caused from the interaction of certain chemicals found in vapes with heat:

The main constituents of the vapour that create the plumes are vegetable glycerin and propylene glycol.

Inhalation of propylene glycol damage small airway epithelial cells in humans, as well as causing DNA damage and cell death. When propylene glycol (and glycerine) is heated, depending on the specific product, it can form aldehydes such as formaldehyde and propionaldehyde, which are known carcinogens. Acute and chronic risks to health including poor oral health, lung damage, cancer, and breathlessness can later follow.<sup>103</sup>

2.87 Furthermore, it was specified that there are limitations to the known health impacts of vapes:

Lack of evidence means their safety for most major outcomes has not been established, including for cancer, cardiovascular disease, reproductive health, mental health, development in children and adolescents, sleep, wound healing, and neurological, endocrine, olfactory, optical, allergic and haematological conditions.<sup>104</sup>

2.88 The Department acknowledged these limitations on safety, stating:

The wide and unpredictable variation in vapes, including unknown manufacturing quality, and the ability of users to customise device settings and vary the quantity and concentration of vaping substances, make it

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<sup>101</sup> See, for example, VicHealth, *Submission 60*, pp. 5–6. See also: Thoracic Society of Australia and New Zealand, *Submission 61*, [p. 2]; Professor Emily Banks et al, *Submission 62*, p. 12; Cancer Council Australia, *Submission 70*, [p. 17]; National Heart Foundation, *Submission 65*, p. 5.

<sup>102</sup> Lung Foundation of Australia, *Submission 8*, p. 5.

<sup>103</sup> Thoracic Society of Australia and New Zealand, *Submission 61*, [p. 2.]

<sup>104</sup> Professor Emily Banks et al, *Submission 62*, p. 4.

difficult to provide a consistent assessment about the safety and effects of vapes as a group.<sup>105</sup>

- 2.89 Professor Anthony Lawler of the Department further elaborated on the history of regulation for the purposes of addressing safety:

As I think we've highlighted, in late 2021 there was a decision by the scheduling delegate under the scheduling framework to schedule it under schedule 4. That was, as with any assessment, in light of the safety, quality and efficacy and, importantly, the potential for risk and toxicity. So that decision was taken at that time based on the clinical evidence. There has not since then been an emergence of clinical evidence that would change that benefit-risk profile, and that is one of the reasons why the proposed regulatory framework outlines a schedule 4 prescription by a medical or nurse practitioner and then dispensing by a pharmacist.<sup>106</sup>

- 2.90 The Department also emphasised the safety measures which would be undertaken under the proposed legislation:

Vapes must comply with enhanced quality and safety standards and be supplied only in pharmacy settings, with a prescription being required to access a vape containing nicotine.<sup>107</sup>

## **The need for greater enforcement and coordination to target the illicit market**

### **Concerns about the illicit market**

- 2.91 Some participants in the inquiry discussed the concerns about illicit products and the black market. As outlined by 360Edge:

Vaping products sold through the black market present a significantly higher risk of harm because they are unregulated. This means they lack quality and safety controls, are easily accessible by youth, are inadequately labelled and may contain harmful substances.<sup>108</sup>

- 2.92 Queensland Network of Alcohol and Other Drug Agencies argued that the current situation with illicit vapes in Australia could be linked to a high level of restriction of the market:

... an appropriate balance needs to be achieved to ensure that there is sufficient regulation in place to support the safety and quality of vaping products in Australia to meet the current market demand, but that this is

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<sup>105</sup> Department of Health and Aged Care, *Submission 1*, p. 6.

<sup>106</sup> Professor Anthony Lawler, Deputy Secretary, Health Products Regulation Group, Department of Health and Aged Care, *Committee Hansard*, 2 May 2024, p. 51.

<sup>107</sup> Department of Health and Aged Care, *Submission 1*, p. 4.

<sup>108</sup> 360Edge, *Submission 9*, [p. 3].

not so restrictive that it supports the continued growth of an unregulated market or a shift back to smoking tobacco.<sup>109</sup>

2.93 Mr Greg Isaacs, owner of Flavourhype Distribution, warned the committee about a potential rise in black market activities:

The majority of my customers have told me that they will most likely resort to the black market or just go back to smoking, because they cannot purchase what they need. Pharmacies are pricing these products to be more expensive than a pack of smokes.<sup>110</sup>

### *Fears of increased criminal engagement in the vaping market*

2.94 Of the proposed legislation, some submitters expressed concerns about the existing black market around illicit nicotine products in Australia and the risk that these reforms might expand these markets.<sup>111</sup> Other submitters also expressed concerns about the increase in organised crime groups seeking to access this market.<sup>112</sup>

2.95 A few submitters highlighted the illicit tobacco market as a cautionary parallel to the proposed vaping reforms and expressed concerns about the risk of firebombings, violence and extortion as a result of heightened criminal involvement in the market.<sup>113</sup>

2.96 Furthermore, Spano Group discussed the need for:

... a more nuanced approach to the regulation of vaping products. It's critical that the Committee consider the causes of this current crisis including the demand for the products and ease of supply by criminal networks in comparison to the barriers an adult currently has to accessing regulated legal products.<sup>114</sup>

2.97 Ritchies Stores also highlighted the need for regulation in order to address the proliferation of illicit goods:

We understand that some consumers will do their best to follow the rules, by obtaining prescriptions from their GPs and purchasing their vaping products from pharmacies as proposed by the Government. However, given the experience with illicit tobacco and the fact that the illegal supply chains

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<sup>109</sup> Queensland Network of Alcohol and Other Drug Agencies, *Submission 11*, p. 3.

<sup>110</sup> Mr Greg Isaacs, Owner, Flavourhype Distribution Pty Ltd, *Committee Hansard*, 2 May 2024, p. 19.

<sup>111</sup> Mr Rohan Pike, *Submission 24*, p. 2. See also: Police Federation of Australia, *Submission 12*, pp. 2–3; Dr James Martin, *Submission 25*, [p. 2].

<sup>112</sup> Dr James Martin, *Submission 25*, [p. 2]. See also: Spano Group, *Submission 63*, [p. 1]; Ritchies Stores, *Submission 64*, [pp. 1–2].

<sup>113</sup> Dr Colin Mendelsohn, *Submission 21*, p. 5. See also: Ritchies Stores, *Submission 62*, [p. 2].

<sup>114</sup> Spano Group, *Submission 63*, [p. 2].

for vaping products are already well-established, illegal products will still be available and sold to adults and children.<sup>115</sup>

2.98 Mr Michael Outram, Commissioner of the Australian Border Force (ABF) also expressed support for the bill, stating:

Why I'm so supportive of this approach is because we've got the permit scheme that is different, and it's a prohibition. We're not just taxing it, we're actually prohibiting it, but with a nuance around the permit scheme. So we're not preventing Australians who legitimately need access to these goods from getting hold of them. Or there may be challenges that we've talked about. But from a border point of view and an enforcement point of view, we've got the benefits of a prohibition and the permit scheme coming in together, which makes the regulatory work much simpler for us.

If it's just open, we'll have far more of these goods coming into the border. It'll be harder for us to discern which is legitimate and which is not. It will also be easier for organised crime to divert legitimate goods into the illicit market.

What I'm saying here is that I think this scheme gives us the best chance to limit the size of this market and the access to these goods for kids.<sup>116</sup>

2.99 Mr Outram also used the comparison to tobacco to explain why this legislation would make enforcement simpler and more effective:

It is very hard for our officers to discern what's legitimate and what's not, because tobacco is a legal product in many cases. We have to go through a lot of processes and steps, regulatory wise, to determine whether the import is lawful or not. In this case, with this prohibition measure in place, we'll have a very simple list of permits that are in place. Everything else won't be permitted. We won't have to get it examined, we won't have to get it taken to laboratories and we won't have to get it tested. If it's a vape or it contains vaping products, we can seize it and destroy it, to put it simply.<sup>117</sup>

2.100 The Department further explained how the bill was intended to address issues of the illicit market:

Further, the Bill would make unlawful vapes easier to detect and reduce opportunities for illicit trade. This is because nicotine content would not need to be demonstrated through laboratory testing before action could be taken under the TG Act. This would address the common practice observed throughout the industry of concealing and otherwise misrepresenting nicotine content, which has hampered enforcement efforts both domestically and at the border. The intention of the new offences and civil

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<sup>115</sup> Ritchies Stores, *Submission 62*, [p. 2].

<sup>116</sup> Mr Michael Outram APM, Commissioner, Australian Border Force, *Committee Hansard*, 2 May 2024, p. 41.

<sup>117</sup> Mr Michael Outram APM, Commissioner, Australian Border Force, *Committee Hansard*, 2 May 2024, p. 43.



penalty provisions is to deter unlawful conduct, among commercial and criminal groups seeking to profit from vapes.<sup>118</sup>

2.101 The ABF further elaborated on the benefits of the proposed legislation in its support for the proposed powers for seized vaping goods to be dealt with in a manner that is deemed appropriate by the Comptroller-General.<sup>119</sup> As the ABF described:

This can include the immediate destruction of the goods which provides streamlined administrative processes and reduced storage time.

The ABF strongly supports this provision of the Bill, as the ability to seize and immediately destroy vaping goods would significantly enhance the ABF's ability to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.<sup>120</sup>

2.102 Also, other participants to the inquiry noted that concerns about the illicit market continuing to operate should not stop the progression of this legislation. Professor Tanya Buchanan emphasised this by stating:

... we know that, even in countries where they have had so-called retail sales, that hasn't stopped an illicit environment. I think we need to be really clear that illegal sales will continue in a retail environment. In the UK, intelligence-led testing found one in three shops knowingly sold vapes to people under the legal age and that, in those instances, we also saw the illegal sale of products that don't meet regulatory standards in those countries. So we understand that there is not a perfect system that will absolutely stamp out illegal sales, but this bill will enable all enforcement agencies to take a more streamlined approach because it will be clear that, if something is being sold outside of the prescription pathway model, it is an illegal product and it can be seized.<sup>121</sup>

### **The need for greater clarification around commercial possession**

2.103 Submitters called for more specific clarification around commercial possession limits, to ensure that individuals with vaping goods for personal use were not inadvertently targeted by this legislation.<sup>122</sup>

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<sup>118</sup> Department of Health and Aged Care, *Submission 1*, p. 8.

<sup>119</sup> Department of Home Affairs, *Submission 2*, p. 4.

<sup>120</sup> Department of Home Affairs, *Submission 2*, p. 4.

<sup>121</sup> Professor Tanya Buchanan, Chief Executive Officer at Cancer Council Australia, *Committee Hansard*, 1 May 2024, p. 5.

<sup>122</sup> VicHealth, *Submission 60*, p. 16. See also: Cancer Council Australia, *Submission 70*, [p. 20]; Alcohol and Drug Foundation, *Submission 7*, p. 2; Lung Foundation of Australia, *Submission 8*, p. 10; Queensland Network of Alcohol and Other Drug Agencies, *Submission 11*, p. 3; Australian Alcohol and other Drugs Council, *Submission 20*, [p. 2].

2.104 As specified by the Lung Foundation of Australia, this clarification is needed to avoid:

... the criminalisation of individuals for personal possession of e-cigarettes, particularly for young people who have been targeted with these products. Criminal convictions for personal use can be detrimental to education and employment opportunities, and risk ongoing stigma.<sup>123</sup>

2.105 Some submitters recommended the specification of the amounts for a commercial quantity that the government intends to include in the regulations be publicly clarified, to ensure certainty that individual vape users will not be criminalised.<sup>124</sup>

2.106 Professor Emily Banks further stated that this was necessary to ensure that the enforcement of the legislation was targeted at those involved in supply, rather than individual users experiencing nicotine addiction:

It is important to note that e-cigarettes are highly addictive and that those using e-cigarettes are often addicted as children, which makes it particularly important that any punitive measures are clearly targeted at those supplying e-cigarettes, rather than at individual users.<sup>125</sup>

2.107 The Department further clarified this as the intended purpose of the bill, stating:

Importantly, the controls in the Bill would not prohibit possession of vapes for personal use. The Bill would not penalise personal possession. Individuals will not be penalised for vaping. The Bill only seeks to prevent possession for the purposes of commercial supply.<sup>126</sup>

2.108 At a hearing, Dr Erin Lalor of the Australian Alcohol & Other Drugs Council told the committee:

We also see it as important that the commercial quantities within the bill are defined in regulation, as there needs to be some flexibility in defining these, particularly given that we are still learning how much of a product an individual may have for personal use.<sup>127</sup>

2.109 Dr Bridget Gilmour-Walsh of the Department further clarified the proposed mechanism for determining a commercial quantity at the hearing, stating:

We have been doing some work on what method we would use to determine what a commercial quantity should be, looking at (a) what a person might reasonably need to use and (b) what sort of quantities a person might reasonably hold. We were thinking that perhaps something around three

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<sup>123</sup> Lung Foundation of Australia, *Submission 8*, p. 10.

<sup>124</sup> VicHealth, *Submission 60*, p. 16. See also: Cancer Council Australia, *Submission 70*, [p. 20]; Australian Alcohol and other Drugs Council, *Submission 20*, [pp. 2–3] and [p. 4].

<sup>125</sup> Professor Emily Banks et al, *Submission 62*, p. 5.

<sup>126</sup> Department of Health and Aged Care, *Submission 1*, p. 9.

<sup>127</sup> Dr Erin Lalor, Chief Executive Officer, Australian Alcohol & Other Drugs Council, *Committee Hansard*, 2 May 2024, p. 10.

months supply might be adequate, taking into account that people in remote areas might need to stock more than the one-month standard, but we're open to having further discussions about that and receiving further information about that to inform that decision.<sup>128</sup>

### **Coordination across jurisdictions**

2.110 The bill reflects the commitment across the Commonwealth and state and territory governments to address the challenges of illicit vapes and the harms they cause. The Department emphasised the need for action given the widespread issues of non-compliance with the existing legislation:

Normalisation of vaping has the potential to disrupt Australia's significant achievements in tobacco control. Evidence of widespread non-compliance with existing Commonwealth, state and territory laws also underscores the need for action.<sup>129</sup>

2.111 The responsibility for regulatory settings related to vapes is shared amongst the Commonwealth and states and territory governments and this bill represents a coordination of powers to ensure the efficacy of enforcement and compliance.<sup>130</sup>

2.112 As highlighted by the Department, this legislation is the culmination of coordinated work to address these issues, including an agreement between Health Ministers to extend the operation of the Therapeutic Goods Act to restrict the importation, domestic manufacture and supply of all vapes.<sup>131</sup>

2.113 There was also further agreement amongst state and territory health ministers that the Commonwealth would lead the enforcement of new importation and manufacturing controls, advertising controls, and controls on therapeutic vapes; the states and territories would lead the enforcement efforts at the point of wholesale and retail supply.<sup>132</sup> The bill would enable further enforcement powers for state and territory governments and facilitate information sharing between states and territories and other compliance and enforcement bodies.<sup>133</sup>

2.114 As highlighted by the Department:

All Australian governments are working together to support a coordinated and comprehensive national response to the regulation of vapes through stronger legislation, enforcement, education and support.<sup>134</sup>

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<sup>128</sup> Dr Bridget Gilmour-Walsh, Principal Legal and Policy Adviser, Health Products Regulation Group, Department of Health and Aged Care, *Committee Hansard*, 2 May 2024, p. 50.

<sup>129</sup> Department of Health and Aged Care, *Submission 1*, p. 2.

<sup>130</sup> Department of Health and Aged Care, *Submission 1*, pp. 5.

<sup>131</sup> Department of Health and Aged Care, *Submission 1*, pp. 4–5.

<sup>132</sup> Department of Health and Aged Care, *Submission 1*, pp. 4–5.

<sup>133</sup> Department of Health and Aged Care, *Submission 1*, pp. 9.

<sup>134</sup> Department of Health and Aged Care, *Submission 1*, p. 5.

2.115 The Lung Foundation of Australia highlighted the importance of this coordinated approach, noting that it would ensure appropriate and effective enforcement by states and territories.<sup>135</sup> For example, Mr Scott Phillips of Kidsafe Western Australia explained to the committee ‘some harmonisation, some consistency of legislation across the country is really important’ and that, there needs to be ‘clear penalties’.<sup>136</sup>

### *National Vaping Working Group*

2.116 To further consolidate coordination mechanisms in relation to this issue, the National Vaping Working Group was established in November 2023 and oversees the development and implementation of a National Vaping Enforcement Framework.<sup>137</sup>

2.117 The National Vaping Working Group includes senior health and law enforcement representatives from the Commonwealth, including the TGA and ABF, as well as all states and territories.<sup>138</sup> The Department of Home Affairs commented that:

The intent of the Bill will support the strong collaborative compliance and enforcement approach being undertaken by the NVWG to deliver an end-to-end compliance model that closes regulatory and legislative gaps. This will be achieved by preventing the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable vaping goods, irrespective of nicotine content or therapeutic claims, across all levels of the supply chain. The appointment of Australia’s first Illicit Tobacco and E-cigarette Commissioner will also complement these efforts.<sup>139</sup>

2.118 Secretary Susan Pearce, in her capacity as co-chair of the National Vaping Working Group, further elaborated on the importance of this mechanism for coordination:

... part of the work that we're doing through the working group is very much about clarifying roles and responsibilities between health departments and other agencies. Not all states and territories look the same in respect of who does the compliance and enforcement work on the ground. It's really about the partnering, as I mentioned before, and sharing information—for example, the MOU that New South Wales Health is establishing with New South Wales Police. We're able to share that information with other jurisdictions so that they can look at how that applies to their own jurisdiction. As Commissioner Outram has already mentioned,

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<sup>135</sup> Lung Foundation of Australia, *Submission 8*, p. 10.

<sup>136</sup> Mr Scott Phillips, Chief Executive Officer, Kidsafe Western Australia, *Committee Hansard*, 2 May 2024, p. 5.

<sup>137</sup> Department of Health and Aged Care, *Submission 1*, p. 10.

<sup>138</sup> Department of Health and Aged Care, *Submission 1*, p. 10.

<sup>139</sup> Department of Home Affairs, *Submission 2*, p. 5.

we are looking at the issues around the disposal and transport of vape seizures. We're really keen to make sure that all of our states and territories have this framework but also that there is flexibility within it that allows them to apply it to their own local jurisdiction so that it meets their needs.<sup>140</sup>

### **Committee view**

- 2.119 Australia has long been regarded as a world leader in tobacco control, from the original reforms to tobacco advertising, through to tobacco plain packaging reforms. The proposed reforms outlined in this bill are an opportunity to continue Australia's role as a global leader in tobacco control. It is especially important to ensure that the progress achieved to date is not lost through complacency about the threat posed by vaping, especially to young Australians.
- 2.120 The committee undertook this inquiry in accordance with its obligations under the World Health Organization Framework Convention on Tobacco Control and reaffirms its commitment to its work in assessing this legislation in a transparent and accountable manner.
- 2.121 Throughout the inquiry, the committee heard of the extent of the public health harms that are already attributable to the use of vaping products. Now is the time for action, as intervention must occur before the harms caused by vaping are allowed to continue and the harms of nicotine addiction are perpetuated for another generation. These harms are already visible and alarming, notwithstanding that it is not currently possible to know the full extent of the health harms caused by vaping.
- 2.122 The committee was particularly disturbed to hear of the prevalence of illicit vaping use amongst children and young people. The evidence shows a new generation of Australians are becoming addicted to nicotine through these products. The committee heard of the significant impacts of such addiction on the physical and mental health of young people. The committee is deeply concerned that these products are being intentionally targeted at children through their design, advertisements and the deliberate location of retailers selling these vapes near schools and high traffic areas.
- 2.123 The committee acknowledges the intention of vaping products may have been as smoking cessation devices but is of the view that the current situation without effective regulation or enforcement mechanisms represents a significant danger to the Australian community - especially young Australians - and the nation's progress to date in tobacco and nicotine product reforms. While vapes have been shown to provide smoking cessation support in some instances, it is clear that the most widespread use of these devices currently is not for these purposes.

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<sup>140</sup> Ms Susan Pearce, Secretary, NSW Health and Co-Chair of the National Vaping Working Group, *Committee Hansard*, 2 May 2024, pp. 39–40.

- 2.124 The proposed pathway for accessing vaping devices as a therapeutic product ensures the vaping products are provided in a safer and regulated manner that is in accordance with all other therapeutic goods in Australia. The committee notes the views of some inquiry participants, mostly adults who have quit smoking through vaping products, who believe that the proposed model will make it difficult for them to access vapes and are fearing that it will lead them to smoke cigarettes again. However, the committee is of the view that the proposed model will enable them to access the vaping products they need in a therapeutic way similar to other Nicotine Replacement Therapies. The Committee notes suggestions from some witnesses that pharmacists could play a greater role in providing access to therapeutic vaping goods that may warrant further consideration. The Committee further notes that this suggestion could improve ease of access to therapeutic goods.
- 2.125 The Committee acknowledges concerns raised by some participants regarding the potential for individuals accessing vaping products to be inadvertently captured by offence provisions in the bill. The Committee notes, however, evidence from a range of witnesses regarding personal possession defences provided in the Bill and the objectives of the bill outlined by the Minister and Department of Health and Aged Care.
- 2.126 Moreover, the committee acknowledges the concerns that were raised across the inquiry about the emergence of the illicit market and the increase of unregulated and harmful products that make false claims about nicotine content. It is concerning to the committee that there is a legal loophole which enables this illicit market to function, with limited enforcement remedies available to law enforcement and health agencies. The committee recognises the bill as an effective mechanism to address these legal loopholes and is reassured to hear from enforcement agencies that the legislation will “significantly enhance” the ability of law enforcement and health authorities to crack down on imported vaping goods and illicit operators who seek to profit from these harmful devices.
- 2.127 Evidence the committee received crystallised the utmost importance of action being taken to address the widespread issue of illicit vapes to protect Australia’s progress in tobacco control and harm reduction and to ensure future generations continue to minimise their consumption of tobacco products.
- 2.128 The legislation will also enact mechanisms that ensure comprehensive coordination across the Commonwealth, state and territory governments. Having an established national coordination framework will ensure the responsiveness and effectiveness of enforcement and detection efforts in relation to these illicit products that cause so much harm.
- 2.129 Importantly, the commitment from the government to deliver a comprehensive public health awareness campaign and further funding for smoking cessation support services complements the measures in the bill and ensures that there

will be effective support for those who need it to access support to help them quit nicotine products.

- 2.130 The committee acknowledges the concerns expressed by some submitters and the Scrutiny Committee about lack of definition of what constitutes a commercial quantity of vaping goods as this will be set out in regulations. However, the committee accepts the evidence regarding the importance of giving the Minister flexibility to set a commercial quantity to ensure an effective response to industry attempts to subvert enforcement.
- 2.131 The proposed legislation represents a comprehensive and considered approach to address all facets of the issue, complementing Australia's National Tobacco Strategy: providing appropriate enforcement mechanisms to address illicit vaping products, targeting those who seek to gain commercially from the vaping market and providing holistic cessation support for people addicted to nicotine products.
- 2.132 Ultimately, this bill is about protecting young Australians from the very real and alarming harms of vaping. As such, the committee recommends that the bill be passed.

### **Recommendation 1**

- 2.133 The committee recommends that the bill be passed.**

**Senator Marielle Smith**  
**Chair**





## **Additional Comments - Australian Greens**

- 1.1 The Australian Greens are deeply concerned about increasing rates of vaping and see increasing nicotine dependence rates as a significant public health problem. We acknowledge that the status quo in Australia is far from ideal. It's unacceptable that children have access to vapes, and vaping products that have been entering Australia are unsafe, falsely labelled and have dangerous unknown ingredients.
- 1.2 The Australian Greens were strongly supportive of sending this legislation to a fulsome Senate inquiry. As what is proposed in this legislation will be world-leading, such a big change must be scrutinised by the parliament and the community.
- 1.3 The Greens do not support the prohibition of vapes for adults and instead will work towards a carefully regulated scheme that focuses on public health outcomes, reducing harm and minimising the use of vaping products.
- 1.4 We appreciate the work of the committee secretariat and thank all those who took the time to submit to the inquiry; particularly those who suggested changes to the proposed legislation.
- 1.5 The Australian Greens are considering the majority report, and based on the evidence presented at the inquiry will seek to propose amendments to the legislation.
- 1.6 Our additional comments are to highlight some of those suggestions made by health professionals, peak representative organisations, and consumers that in their view would improve the legislation.

### **Ensuring personal possession is not criminalised**

- 1.7 The committee heard from multiple witnesses during this inquiry as to the importance of ensuring that individuals who have vaping products for personal use are not criminalised as a result of this legislation.
- 1.8 There was discussion that a definition of personal use must be defined in consultation with lived experience, and there must be an acknowledgement that such a quantity acknowledges that some consumers, including those in rural and regional areas, have limited access to pharmacies.
- 1.9 Many stakeholders raised the importance of defining the term 'commercial quantity' in regulations to allow for adjustments based on observed outcomes of the Bill. It is paramount that the regulations are drafted through a rigorous and transparent process that considers the input of people with lived experience. The Greens call on the Government to release a visibility draft of the Regulations before they are introduced into Parliament to allow sufficient opportunity for feedback from the public.

- 1.10 The Australian Alcohol and Other Drugs Council submission recommended extending the exemption for personal use to individuals in possession of any amount of vaping products. Such an amendment would bring the legislation in line with the *Public Health (Tobacco and Other Products) Act 2023*, which includes a blanket exemption for personal use.
- 1.11 From the Alcohol and Drug Foundation submission to this inquiry, regarding the personal use exemption:
- ... lack of clear definitions of commercial and personal use quantities can impact how this is enforced, which may lead to certain communities being disproportionately affected by criminal sanctions.
- 1.12 The Alcohol and Drug Foundation recommended to the committee that charges should be placed on accused parties based on evidence of supply rather than possession. Additionally, it was suggested that the legislation could consider a total exemption for personal use which would safeguard the criminalisation of consumers.

### **Burden of proof**

- 1.13 The Australian Greens acknowledge the work of the Senate Standing Committee for the Scrutiny of Bills around the reversal of the evidential burden of proof which would result in, among other things, individuals being required to prove their innocence regarding possession offences rather than prosecution being required to prove guilt. From the Scrutiny Digest 5 of 2024:
- The committee welcomes the inclusion of an explanation against each of the reverse burden defences in the bill's explanatory memorandum. However, the committee's view is that in most of these cases, it is not apparent that the matters are matters peculiarly within the defendant's knowledge, or that it would be significantly more difficult or costly for the prosecution to establish the matters than for the defendant to establish them.
- 1.14 There is a non-zero chance of this resulting in the criminalisation of users of illegally obtained vapes despite the personal use exemption. This is because providing evidence of personal use for products obtained without a prescription would cause difficulty for most consumers, yet they would be required to do this to avoid being charged for possession.

### **Ensuring appropriate Quit supports**

- 1.15 Over the course of the inquiry, the Committee heard from witnesses about the need for comprehensive wrap-around services to support both people who are attempting to quit nicotine and those who are in a position to assist people who are attempting to quit.
- 1.16 The Australian Council of State School Organisations gave evidence on the need for properly targeted, well-rounded information to teachers, principals, school leaders and families.

- 1.17 As noted in item 2.65 of the committee's report, Associate Professor Raglan Maddox also gave evidence on the need for training and funding to improve referral pathways to tobacco and nicotine cessation supports.
- 1.18 The Australian Greens support greater investment in quit support services, including additional services and resources to meet the needs of schools, parents, children, First Nations people, health practitioners and other priority cohorts.

### **Investment in waste and recycling**

- 1.19 The environmental impacts of vaping products were discussed at the public hearings.
- 1.20 Professor Emily Banks submitted to the inquiry noting that waste management of vaping products is an increasingly difficult challenge in Australia, with many vapes and vape components designed to be single-use. She also submitted that lithium-ion batteries and e-liquid pose a threat to the environment in the form of hazardous chemical waste when disposed of incorrectly.
- 1.21 Professor Tom Calma gave evidence of the significant concern about vaping products ending up in streets and waterways, especially in First Nations communities.
- 1.22 There is no nationally coordinated approach to the safe disposal of vaping products, despite many current users being required to dispose of all non-prescription vaping products under this Bill.
- 1.23 To address the environmental damage, and to ensure the mass disposal that would be required under this Bill, The Australian Greens supports investment in national recycling programs, including a program for vaping products.

### **Restriction of advertisement of vaping products to medical practitioners**

- 1.24 The Australian Greens support having a well-resourced system to manage the marketing of pharmaceuticals and therapeutic goods. The Committee heard from multiple witnesses about the unethical marketing and promotion tactics of the tobacco and e-cigarette industries. Health practitioners mustn't be motivated by anything other than health outcomes when treating nicotine addiction.
- 1.25 In their submission, the Cancer Council Australia recommended that the Bill be amended to provide safeguards for health practitioners to ensure that they are protected from tobacco and vaping advertising and promotion from commercially motivated parties. From the Cancer Council Australia:

Vaping products carry a different risk profile to other prescription-only medicines, given their status as 'unapproved' (unregistered) therapeutic goods and the broader public health risks they carry. It is the Cancer Council's view that specific restrictions on the marketing of unregistered vapes to health professionals are justified in order to reflect the increased potential for harm arising from the use of a product that has not undergone

the rigorous testing required for entry on the ARTG [Australian Register of Therapeutic Goods].

**Senator Jordon Steele-John**

## Additional Comments - Coalition Senators

- 1.1 Coalition Senators note the recommendations of the majority report and reserve our final position while this policy makes its way through our internal processes.
- 1.2 Coalition Senators want to thank the witnesses who attended public hearings, and all who took time to make a submission to this inquiry. Their evidence was crucial in guiding us through a very important issue.
- 1.3 Coalition Senators believe that vaping in Australia needs to be viewed through the prism of doing more to ensure young people, especially children, do not have access to vaping products while at the same time not creating barriers for responsible adults who wish to use vaping as a smoking cessation or to treat their addiction.
- 1.4 The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 prohibits the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic (non-nicotine) and prohibits the domestic manufacture, commercial possession and advertisement of non-therapeutic (non-nicotine) disposable vaping goods.
- 1.5 Coalition Senators strongly support the stated intent of the legislation to 'address the growing risk posed by vaping in Australia, particularly to youth and young adults'.<sup>1</sup> However, concerns have been raised of the potential that this Bill (alongside other legislation and regulations introduced this year) will cause considerable unintended consequences by sustaining an organised criminal black market that risks consumer and community safety.
- 1.6 Coalition Senators note that despite the retail sale of nicotine e-cigarettes having never being legal in Australia, the vaping rate among young people aged 14-17 has increased from 1.8% in 2019 to a record high of 9.7% in 2022-23.<sup>2</sup>
- 1.7 Coalition Senators note that the existing prescription only model has failed to address the exponential growth in underage vaping.
- 1.8 Coalition Senators note the proven control framework for tobacco, which has successfully driven Australia's underage smoking rate to a record low.

### Prohibition policy failure

- 1.9 As the current Health Minister has stated, Australia's vaping black market:

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<sup>1</sup> Explanatory Memorandum, p. 1.

<sup>2</sup> Explanatory Memorandum, p. 3.

Is a lucrative source of revenue for criminal gangs who use it to bankroll drug trafficking, sex trafficking and all of their other criminal activities.<sup>3</sup>

- 1.10 Concerningly at the public hearing, the Committee received evidence from criminologist Dr James Martin that:

The consequences of this ban have been disastrous, with nine out of 10 vapers having already rejected the prescription model and instead sourcing their products from the black market.

With around 1.5 million Australians now vaping illegally, the bans have created the second-largest illegal drug market in the country after cannabis and a massive new front in the war on drugs.

- 1.11 Instead of achieving the Health Minister's desired outcome to 'stamp out recreational vaping',<sup>4</sup> Dr Martin stated during the public hearing that:

Law enforcement does not and cannot restrict access to the point that consumers who want these products will be precluded from getting them.

Rather, markets adapt, and supply goes underground, where it is even more difficult to police. The illegal products that are supplied by the black market are unregulated, meaning that they are more potent, more addictive and more dangerous than their legal alternatives.

Increasing penalties and heavier policing do not stop criminal actors from entering the market. They simply allow them to charge more for their services and increase the profits available to organised crime.

- 1.12 Evidence from the Police Federation of Australia supported the evidence of Dr Martin that the elimination of the illegal vaping black market through, effectively, prohibition was not achievable:

Senator CADELL: Mr Weber, in summary, the police force does amazing work and a lot of work, especially [inaudible] domestic violence. With the resources and training you have now, and with all the other demands on you, could you enforce this to eliminate illegal vaping in these laws across the country?

Mr Weber: No; not at all.

## **Western Australia's existing vaping ban**

- 1.13 The current Health Minister has previously stated one of the purposes of this legislation was to close an enforcement 'loophole':

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<sup>3</sup> Department of Health and Aged Care, *Radio interview with Minister Butler and Rafael Epstein on ABC Radio Melbourne Mornings – 23 April 2024*, 23 April 2024, [Radio interview with Minister Butler and Rafael Epstein, ABC Radio Melbourne Mornings - 23 April 2024 | Health Portfolio Ministers | Australian Government Department of Health and Aged Care](#) (accessed 8 May 2024).

<sup>4</sup> Department of Health and Aged Care, *Minister for Health and Aged Care – press conference – 2 May 2024*, 2 May 2024, [Minister for Health and Aged Care - press conference - 2 May 2024 | Health Portfolio Ministers | Australian Government Department of Health and Aged Care](#) (accessed 8 May 2024).

Currently there is a loophole in place that means it is legal to sell non-nicotine vapes.

What we're doing now is closing that loophole. All of these disposable vapes, no matter what they present as, will be illegal as we start to put these regulations in place.<sup>5</sup>

- 1.14 At the public hearing, the Committee was advised by Kidsafe Western Australia this loophole did not exist in Western Australia:

Senator CADELL: In WA they've made the sale of all vapes illegal – nicotine and non-nicotine vapes – through state legislation, haven't they?

Mr Phillips: Yes.

- 1.15 Consistent with evidence provided by the Police Federation of Australia and criminologist Dr Martin, a legislated ban on the sale of all vaping products, which this Bill seeks to achieve, was unenforceable in Western Australia and made no difference to the accessibility of black market vaping products:

Senator CADELL: There's an article in the West Australian, from Tuesday 6 February, that says vape stores are still operating in Fremantle and there are still two vape stores operating within 200 metres of a school. Have you seen any enforcement to enforce these laws and stop people selling vapes?

Mr Phillips: I think it comes down to the capacity to do that enforcement. Quite often it is about what resources there are to do that. I'm aware that there is enforcement, but, specifically for those two situations, I couldn't answer that.

Senator CADELL: The article goes on. They went to specific stores and asked for berry flavoured product containing nicotine and were successful in eight stores. Separately, a University of Notre Dame study found that nine in 10 vape shops in Perth are within one kilometre of schools. This is despite having prohibition laws on the sale of vapes, isn't it?

Mr Phillips: Yes

## Consumer and community safety

- 1.16 According to the Office of Impact Analysis' 'Proposed Reforms to the Regulation of Vapes' impact analysis associated with this legislation, the number of adult vapers who have a nicotine prescription for vapes is as low as 3%, indicating that as many as 97% of adult vapers are purchasing unregulated products from the black market.<sup>6</sup>

<sup>5</sup> Department of Health and Aged Care, *Minister for Health and Aged Care – press conference – 28 November 2023*, 28 November 2023, <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-28-november-2023> (accessed 8 May 2024).

<sup>6</sup> Department of Health and Aged Care, *Proposed reforms to the regulation of vapes – Impact Analysis*, October 2023, [Impact Analysis - Proposed reforms to the regulation of vapes.PDF \(pmc.gov.au\)](https://www.pmc.gov.au/impact-analysis/Proposed-reforms-to-the-regulation-of-vapes) (accessed 8 May 2024).

1.17 The lack of regulation on flavourings, nicotine strength and ingredients were consistent themes raised throughout public hearings, with Cancer Australia stating:

Prof. Milch: All vapes are different. That's part of the problem – the colourings, the flavourings, of vapes are unregulated, and there are different chemicals in many different vapes.

1.18 These concerns of consumer safety from unregulated products were also raised by regulated vaping manufacturers in public hearings, such as From the Fields Pharmaceutical, who currently wholesale through the limited lawful medical prescription pathway:

Senator KOVACIC: What do you think, then, are the risks of a regulatory framework where the only choices are a therapeutic vape or an illegal vape?

Mr David: You just need to look at the numbers. Today there are anywhere from one to 1.7 million adults who are vaping...

Unfortunately, their access point has been through unregulated illegal products, which are far more dangerous than regulated products.

1.19 Coalition Senators share the considerable concern expressed by the Minister for Education that 'every teacher, every principal at a high schools tells me vaping is one of the biggest behavioural issues in their schools'.<sup>7</sup>

1.20 The potential of poisoning from unregulated products was identified in public hearings by Kidsafe Western Australia:

Mr Phillips: Specifically, from a kid-safe point of view and an injury prevention point of view, the proliferation of these unregulated devices into the market has raised some concerns, particularly for younger children, around nicotine poison.

We're very aware that nicotine is a very toxic chemical for children. We're also aware that it can be inhaled, absorbed or ingested. Small amounts of high levels of nicotine can have major effects on a child.

1.21 Evidence received by tobacco treatment specialist Dr Mendelsohn, summarised the intersection between consumer and community safety risks created by the Australian Government's medical prescription model for vaping products in the public hearings:

Dr Mendelsohn: Ninety per cent of current vapers have rejected the legal pathway, and only a small number of doctors are willing to prescribe nicotine.

This has predictably created a thriving and dangerous black market controlled by criminal networks which are selling high nicotine, unregulated products.

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<sup>7</sup> Ministers' Media Centre, Ministers of the Education Portfolio, *Press Conference – Sydney Transcript*, 10 April 2024, [Press Conference - Sydney | Ministers' Media Centre \(education.gov.au\)](https://www.education.gov.au/press-conference-sydney-ministers-media-centre) (accessed 8 May 2024).



There's been escalating violence with that. This has also been the key driver of youth vaping.

- 1.22 The risks to community safety from organised criminal gangs selling unregulated vaping products were further reinforced by evidence from the Police Federation of Australia stating:

Senator URQUHART: The question I want to ask you specifically is: why have law enforcement agencies struggled to contain the rise of illicit vaping products?

Mr Weber:...I think our question – and you've raised this in a roundabout way – is: what does the government want out of this policy?

For us, it's created a crime. I never would've thought, five or 10 years ago, that I'd be even discussing any of these issues about illicit tobacco or vaping; yet we are sitting here talking about it now.

It is, as the good doctor said, a real industry for crime and organised crime. We're actually putting more people in harm's way of the health issues.

- 1.23 The extent of the harm caused to community safety from the unregulated trade was detailed in public hearings by criminologist Dr Martin:

Dr Martin: The battle for control of this trade has resulted in serious criminal violence, with over 70 fire-bombings and multiple homicides witnessed around the country in the last 12 months alone.

### **Inquiry process and international approaches**

- 1.24 Coalition Senators raise serious concerns about how Government Senators influenced this committee process, particularly regarding the lack of detailed consideration of international experts and affected stakeholders.
- 1.25 Over 60 submissions were published less than two days before public hearings and less than a day and a half of public hearings were held despite this inquiry receiving over 200 written submissions.
- 1.26 Coalition Senators note the apparent contempt for considered policy-making, ambivalence toward legitimate stakeholders' concerns, and a focus on wrong priorities that has become a hallmark of the Albanese Government.
- 1.27 Through submissions, we received written evidence that over 70 fire-bombings and multiple homicides have occurred due to the black market trade in nicotine products and that lawful businesses have been subjected to community violence of the black market trade, however, none of these submitters were invited to provide evidence in public hearings.

- 1.28 Coalition Senators note that the Royal Australian College of General Practitioners states, Australia is the only country in the world to restrict access to nicotine vaping products on a prescription-only basis.<sup>8</sup>
- 1.29 Despite the Australian Government policy being a global outlier and the dramatic increase in youth vaping under this policy framework, not a single international expert who submitted to the Committee was invited to provide evidence.
- 1.30 Organisations such as Action for Smokefree 2020 Aotearoa New Zealand (ASHNZ) whose patron is former New Zealand Labour Prime Minister the Rt Hon Helen Clark ONZ SSI PC, were denied an opportunity to appear in public hearings and discuss their written submissions, which stated:

New Zealand's vaping regulations were passed in 2020 and came into force from 2021. Since then, regulations have continued to be strengthened.

Note that since the formal legislation to legalise vaping as a regulated consumer product, regular youth vaping has declined for two consecutive years.

New Zealand has seen very little evidence of an organised illicit vape market. There is little incentive to operate an illicit supply chain at any commercially viable scale due to effective competition from the legal marketplace.

The regulated model also provides greater safety for consumers, and people vaping to quit. Unlike Australia where 80% of vapes are estimated to be illicit, the regulation model in New Zealand allows people to have clear sight over the provenance of their vape, purchase from experts in specialist stores, and have a clear expectation around what to do if their product is faulty or problematic.

- 1.31 Professor Ann McNeill of Kings College London, submitted:

Furthermore, the medical prescription requirement appears cumbersome and unlikely to be a workable option for people who smoke and particularly some of the groups with very high smoking prevalence, such as people with mental illness.

- 1.32 Professor Nancy A. Rigotti, MD, Professor of Medicine at Harvard Medical School based at Massachusetts General Hospital in Boston, MA, and Tobacco Policy Scientific Advisory Committee Member for the U.S. Food and Drug Administration's Center for Tobacco Products, through a written submission outlined:

Australia's underlying prescription-only regulatory model for e-cigarettes has failed to make them readily available to smokers whose lives could be saved.

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<sup>8</sup> Anastasia Tsirtsakis, 'Have GPs been supported for vaping to go prescription-only from October?', *newsGP*, 26 August 2021, [RACGP - Have GPs been supported for vaping to go prescription-only from October?](#) (accessed 8 May 2024).

Australia should consider switching to a risk-proportionate, adult consumer regulatory model, as other Western countries have done.

- 1.33 The former Director of Research Policy & Cooperation of the World Health Organization, Professor Tikki Pangestu, provided a written submission stating:

Evidence from many countries where vapes are regulated (e.g. New Zealand, USA, UK), have shown significant reductions in youth vaping numbers. Effective regulatory settings within those markets to control youth access to vaping products (licensing and fines, product restrictions, point of sale restrictions, labelling and enforcement activities, etc.) were instrumental in reducing the numbers of youth vapers.

Regretfully, such reductions have not been observed in Australia and perhaps there are lessons to be learnt from these other countries with regards to strategies and policies which are effective in reducing the incidence of youth vaping

In markets where a total ban applies to vaping products, it is inevitable that an illicit 'black market' will become a major problem for the government.

While policy settings could be envisaged to enhance enforcement activity (e.g. stricter and enhanced surveillance capabilities for entry into the country of illicit supplies of electronic cigarettes, increasing fines for selling, supplying and for possession, including jail time, etc.) such measures will require significant resources and may prove to be ineffective, almost futile, in the longer term as criminals will almost always be one step ahead in finding innovative ways to supply vaping devices and liquids to the black market.

Domestic measures to curb black market operations also ignores the source of the problem, i.e. the likely external source of these illicit vaping products.

### **Urgent need to stop kids vaping**

- 1.34 Coalition Senators agree that more must be done to prevent children accessing vapes, and to assist those children who currently have vaping addictions to transition away from their habit.
- 1.35 This legislation seeks to close current loopholes being used to import, manufacture and supply non-therapeutic vapes, which are then being illegally sold to people under the age of 18.
- 1.36 It is generally accepted that most vapes that claim to be nicotine free contain nicotine, along with other dangerous chemicals. This is resulting in a new generation of young Australians being inadvertently addicted to nicotine.

### **Personal use and harmonisation of legislation**

- 1.37 Coalition Senators are concerned that this legislation will create a scenario where law abiding citizens are caught up in the criminal justice system for owning or carrying a vape. In evidence given at a public hearing, drug and alcohol peak bodies expressed concern that due to a lack of clarity over what

defines personal use and what defines commercial quantities, groups of people could accidentally and inconsistently be punished for possessing a vape.<sup>9</sup>

- 1.38 Coalition Senators believe there is a need for States and Territories to harmonise their legislation so as to ensure national consistency over personal use. Mr Dunne from the Australian Alcohol and other Drugs Council summarised the current problems with the existing settings when he said:

We're finding ourselves in this position within some states and territories where, if you are stopped by a police officer on the street and you are searched for illicit substances and you are found to have vapes and cannabis, you might receive a counselling diversion for your cannabis, but for your vapes you might face fines of up to \$32,000 or 12 months prison in the ACT or, in Western Australia, up to \$45,000 in fines. So it creates an unalignment between tobacco control legislation, vape control legislation and illicit drugs responses.<sup>10</sup>

- 1.39 Coalition Senators believe it should be the priority of the Federal Government to ensure State and Territory Governments work in unison on this issue, so that a person with a vape in Wodonga is treated the same as someone in Albury, and that penalties for personal use of vapes are fair, proportionate and enforceable.

### **Impact for businesses operating in the current legal market**

- 1.40 The committee heard from three vape store owners who had all started their stores to help people quit smoking after they or their family had quit smoking through vaping.
- 1.41 Coalition Senators note the bill offers no compensation to the vape stores that have expended significant capital to build their businesses within the legal market and will be forced to cease operations if this bill is passed.
- 1.42 Coalition Senators call on the Government to address this issue through appropriate means.

### **Parameters of success**

- 1.43 Coalition Senators are concerned that this is another tranche of vaping legislation under this Government that has no quantifiable measures of success. Evidence shows that about 9 out of 10 vapers are not accessing vapes through the Government's tightened prescription model.<sup>11</sup> The Government have not indicated what reduction in illicit vape use is expected from this additional tranche of legislation that would measure it as a successful policy measure. Without quantifiable measures of success there is no way to tell if this legislation is reaching its objectives.

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<sup>9</sup> *Committee Hansard*, 2 May 2024, pp. 9–16.

<sup>10</sup> *Committee Hansard*, 2 May 2024, p. 13.

<sup>11</sup> *Committee Hansard*, 2 May 2024, p. 26.

- 1.44 Coalition Senators consider the Government should be regularly reporting smoking and vaping figures to Parliament in order to determine the success or failure of the prescription model.

## Conclusion

- 1.45 This Committee process has highlighted that the illicit vaping market in Australia is out of control and evidence and commentary from Australian communities and schools have reinforced this view.
- 1.46 As stated by the Police Federation of Australia, legislation has created an illicit market where organised crime is involved, which is turning honest people into alleged criminals or putting them through the criminal system.
- 1.47 This Committee has received no substantive or credible evidence that replicating what has already been demonstrated to have failed in Western Australia – a complete ban on the sale of all vaping products – will address the current vaping black market that has engulfed Australia or, most particularly stop children accessing nicotine vaping products.
- 1.48 Coalition Senators note that vaping models that are in place in other OECD countries, such as the United States, United Kingdom, New Zealand, Canada, and the European Union, to strictly regulate, control, and tax vaping products as an adult consumer product have been proven to control the market and reduce youth vaping.
- 1.49 As stated in public hearings by criminologist Dr Martin:
- Retail licensing, risk-proportionate taxation, strictly enforced age restrictions, plain packaging and bans on advertising, as well as public health campaigns, have successfully reduced rates of both teen and adult smoking and alcohol consumption over the last decade.
- These successes have occurred, without prohibiting these products and generating billions of dollars for organised crime. I therefore urge the committee to heed the lessons of the war on drugs and adopt a similarly pragmatic and realistic approach to the regulation of vapes as we do with other adult consumer products.
- 1.50 Coalition Senators note that this approach and licencing framework was also endorsed by the Police Federation of Australia:
- It would have to be a licensing regime where we could actually enforce that fit and proper people are delivering the tobacco or the vapes.
- 1.51 Coalition Senators also note the evidence provided by experts such as Dr Ron Borland and others in public hearings advocating for alternative models that would allow vapes to be sold in a retail environment:

If we have strong rules about it—about who can actually sell these kinds of products and people losing their licences if they're caught doing the wrong thing—then I think we can effectively restrict the access to young people.

1.52 Coalition Senators reiterate our concern that the current prescription only model, including this Bill, will not deliver the Governments intent to 'address the growing risk posed by vaping in Australia, particularly to youth and young adults'. Nor will it address the serious and worsening black market activity regarding the sale of both illicit tobacco and illicit e-cigarettes.

**Senator Maria Kovacic**

**Senator Ross Cadell**

**Senator Matthew Canavan**

# Dissenting Report - National Party Senators

- 1.1 National Party Senators agree with the Coalition's additional comments and make these additional comments.
- 1.2 Black market vaping products are already rife through our community through a prescription model for nicotine, and the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 will further exacerbate the problem. With 9 out of 10 vapers already bypassing the prescription model by buying potentially dangerous black market products it's clear that the genie is already out of the bottle on vaping. We need to be trying to ensure that we use proven methods to stop children from vaping as we have with alcohol and tobacco products with regulated markets.
- 1.3 Instead of continuing with the same failed prohibition model that has increased the vaping rate among young people aged 14-17 from 1.8% in 2019 to a record high of 9.7% in 2022-23, we urge the Albanese Government to strictly regulate all vaping products under a similar framework as tobacco which has proven to work to reduce youth smoking with the following elements:
  - Licensed retail stores operating under similar rules and regulations to the sale of alcohol and tobacco products;
  - Vaping products sold through these licensed retailers to be approved by government regulators to give parents and adult vapers more confidence they are not sold with dangerous foreign additives such as rat poison or illicit drugs;
  - Vaping products to be sold in plain packaging with health warnings similar to the sale of tobacco products;
  - Vaping products to be regulated not to contain flavours or colours that are deliberately marketed for children;
  - The proceeds of taxation revenue to be quarantined for additional funding for public hospitals, education campaigns to stop youth vaping (particularly through social media channels) and law enforcement measures targeting the black-market.

## **Recommendation 1**

- 1.4 **That the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 not be passed.**

**Senator Ross Cadell**

**Senator Matthew Canavan**





# Appendix 1

## Submissions and Additional Information

- 1 Department of Health and Aged Care
- 2 Department of Home Affairs
- 3 Australian Medical Association
- 4 Australian Nursing and Midwifery Federation
- 5 Cancer Australia
  - Attachment
- 6 Asthma Australia
- 7 Alcohol and Drug Foundation
- 8 Lung Foundation Australia
- 9 360Edge
- 10 National Centre for Youth Substance Use Research
- 11 Queensland Network of Alcohol and Other Drug Agencies
- 12 Police Federation of Australia
- 13 Australian Council of State School Organisations
- 14 Collaboration for Evidence, Research, and Impact in Public Health (CERIPH)
- 15 Kidsafe WA
- 16 The Society of Hospital Pharmacists of Australia
- 17 Mills Oakley
- 18 Western Australia Department of Health
- 19 Westcare
- 20 Australian Alcohol & Other Drugs Council
- 21 Dr Colin Mendelsohn
- 22 Professor Richard Day AM
- 23 Dr Ingrid van Beek AM & Professor Lisa Maher
- 24 Rohan Pike
- 25 Dr James Martin
- 26 Dr Joe Kosterich
- 27 Professor Ron Borland
- 28 Dr Robert Graham
- 29 Associate Professor Michelle Jongenelis
- 30 Emeritus Professor Wayne Hall
- 31 Injury Matters
- 32 Professor Coral Gartner
- 33 Dr Alex Wodak AM
- 34 Emeritus Professor Ian W Webster AO
- 35 Hon Dr Brian Walker MLC
- 36 TSG Franchise Management
- 37 Flavourhype Distribution Pty Ltd

- 38 Shoozitech
- 39 TheCoilMan
- 40 Vape & Grind
- 41 WA E JUICE CO
- 42 A Friend Indeed Australia
- 43 The Vape Company
- 44 Itsvaping
- 45 Mr Liam Sulskis
- 46 Miss Stephanie Travers
- 47 Kristy Webb
- 48 Nicholas Higgs-Poole
- 49 Vaperwave
- 50 Doughbot Enterprises
- 51 Vape Your Way
- 52 Oz-Eliquid
- 53 Oceania Liquid Labs
- 54 Cloud Revolution
- 55 vape4life
- 56 Associate Professor Raglan Maddox
- 57 Australian Council on Smoking and Health
- 58 The Stroke Foundation
- 59 Associate Professor Becky Freeman
- 60 VicHealth
- 61 Thoracic Society of Australia and New Zealand
- 62 Professor Emily Banks et al
- 63 Spano Group
- 64 Ritchies Stores
- 65 National Heart Foundation of Australia
- 66 McCabe Centre for Law and Cancer
- 67 Clinical Oncology Society of Australia (COSA)
- 68 Jones Retail Group
- 69 Cancer Council Queensland
- 70 Cancer Council Australia
- 71 Cancer Council NSW
- 72 Cancer Council Tasmania
- 73 Cancer Council Northern Territory
- 74 Cancer Council Western Australia
- 75 Cancer Council Victoria
- 76 Cancer Council ACT
- 77 Cancer Council South Australia
- 78 Australian Association of Convenience Stores
- 79 Dr Robert Graham
- 80 Professor Dr Sharifa Ezat Wan Puteh

- 
- 81 Dr Ljiljana Čenan  
82 Dr Arifin Fii  
83 Emeritus Professor Robert Beaglehole  
84 Retail and Trade Brands Advocacy  
85 Telethon Kids Institute  
86 Dr Konstantinos Farsalinos  
87 Professor Nancy Rigotti  
88 Australian Medicinal Cannabis Association  
89 Medicinal Cannabis Industry Australia  
90 A/Prof Stuart Thomas  
91 Mr Robert Richter KC  
92 Associate Professor George Laking MD PhD FRACP  
• Attachment
- 93 Professor Riccardo Polosa  
94 Professor Kate Dolan  
95 From the Fields Pharmaceutical  
96 Professor Emeritus Kenneth E. Warner PhD  
97 Leaf House Vape Shop Pty Ltd  
98 Dr Matthew Rimmer  
99 Professor Ognjen Brborovic  
100 Professor Ann McNeill  
101 Professor Jamie Brown  
102 Dr Barbara Davis  
103 Professor Peter Hajek  
104 Asthma and Respiratory Foundation NZ  
105 Imperial Brands Australasia  
106 Action for Smokefree 2020 Aotearoa New Zealand  
107 World Vapers' Alliance  
108 The Vape Store  
109 Mr Justin Leary  
110 Mr Matt Verma  
111 Miss Kat Jones  
112 Mr Anthony Bagala  
113 Mr Darren Stribning  
114 Mr Adam Deane  
115 Name Withheld  
116 Mr Phillip Brooks  
117 Name Withheld  
118 Mrs Bernice Melrose  
119 Mrs Diane Iveson  
120 Name Withheld  
121 Mr Bradley McDermott  
122 Mrs Sarah Maposua

- 123 Mrs Gillian Vallance
- 124 Name Withheld
- 125 Vaper Choice
- 126 Ms Pam Mulholland
- 127 Ms Leah Doxford
- 128 Name Withheld
- 129 Mr Mark Glanville
- 130 Mr Michael Salter
- 131 Name Withheld
- 132 Name Withheld
- 133 Scott McMahon
- 134 Ben Ryan
- 135 Pamela Wright
- 136 Cynthia Sideris
- 137 Cat Wright
- 138 Mrs Karen Gant
- 139 Mr Brad Anthonisz
- 140 Mr Richard Bickerton
- 141 Professor Ian Irvine
- 142 Steel City Vapor
- 143 Victory Vape
- 144 Super Vape Store
- 145 EG Australia
- 146 Professor Tikki Pangestu
- 147 Professor David T. Sweanor
- 148 Taxpayers Protection Alliance
- 149 New Nicotine Alliance UK
- 150 Australian Lottery & Newsagents Association
- 151 Name Withheld
- 152 Mr Ryan Oakley
- 153 Name Withheld
- 154 Name Withheld
- 155 Name Withheld
- 156 Name Withheld
- 157 Name Withheld
- 158 Name Withheld
- 159 Name Withheld
- 160 Morgan's Supermarket
- 161 Kaki Enterprise
- 162 VAPR Pty Ltd
- 163 Emeritus Professor Ruth Bonita Beaglehole
- 164 Ms Jan Walsh
- 165 Ms Fiona Patten

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- 166 Mr Declan Ferguson  
167 Name Withheld  
168 Mr Douglas Leitch  
169 Mr Louis Fairbrother  
170 Mr Brennen Brixen  
171 Name Withheld  
172 Mr Ken McNaughton  
173 Mr Clive Bates  
174 Mr James Warburton  
175 Name Withheld  
176 Mr Shaun Goodwin  
177 Name Withheld  
178 Name Withheld  
179 Name Withheld  
180 Name Withheld  
181 Mr Gregory Primmer  
182 Mr Paul Marshall  
183 Mr Nathan Vail  
184 Ms Lauren Fisher  
185 Mr Rene Heithecker  
186 Environmental Health Australia  
187 Name Withheld  
188 Name Withheld  
189 Mr Steve Marlor  
190 Miss Julie West  
191 Ms Samantha Barratt  
192 Mr Dimitri Milewicz  
193 Name Withheld  
194 Mr Joey Perri  
195 Mr James Kyriakou  
196 Mr Alexander Parks  
197 Name Withheld  
198 Name Withheld  
199 Mr Jack Langdon  
200 Name Withheld  
201 Liber Pharmaceutical  
202 Drug Policy Australia  
203 Australian Secondary Principals' Association  
204 Public Health Association of Australia  
205 Name Withheld  
206 Mr Jacent Hipworth  
207 Mr Bernard Rossi
- 207.1 Supplementary to submission

- 208 Emeritus Professor Simon Chapman AO, Emeritus Professor Mike Daube AO  
and Professor Matthew Peters AM
- 209 Mr Glenn Thompson
- 210 Name Withheld
- 211 Name Withheld
- 212 Mr Eric Williams
- 213 Name Withheld
- 214 Name Withheld
- 215 Mr Konrad Bazan
- 216 Mr Lee Furlong
- 217 Name Withheld
- 218 Name Withheld
- 219 Mr Robert Swan
- 220 Name Withheld
- 221 Name Withheld
- 222 Name Withheld
- 223 Mr Stan Craigie
- 224 Mr John Szaszvari
- 225 Ms Judith Wolters
- 226 Mr Charles McCracken
- 227 Ms Michelle Amee
- 228 Name Withheld
- 229 Mr David Dodd
- 230 Mr Riley Donelan
- 231 Name Withheld
- 232 Mr Timothy Bruschi
- 233 Name Withheld
- 234 Mr Mehmood Essop Bhamjee
- 235 Mr Stephen Noy
- 236 Name Withheld
- 237 Name Withheld
- 238 Name Withheld
- 239 Craig Farquharson
- 240 The Vape Joint
- 241 Name Withheld
- 242 Mr Christopher D Coles
- 243 Mr Andrew Thompson
- 2 Attachments
- 244 Ms Jacinta Parmenter
- 245 Name Withheld
- 246 Name Withheld
- 247 Name Withheld
- 248 Mrs Katherine Hines

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- 249 Name Withheld  
250 Name Withheld  
251 Mr Jason Cheney  
252 Name Withheld  
253 Mr Daniel Markham  
254 Name Withheld  
255 Mr Colin Mannings  
256 Name Withheld  
257 Miss Laura Wilson  
258 Name Withheld  
259 Mr Paul Stevens  
260 Ms Nicole Bryson  
261 Mr Kevin Mancini  
262 Name Withheld  
263 Name Withheld  
264 Christina Fennell  
265 Name Withheld  
266 Mr Darren Rowe  
267 Name Withheld  
268 Mrs Tiffany Kereopa  
269 Retail Enterprise Group  
270 One Vape Australia  
271 Sydney Vape Supply  
272 Ms Sophie Zuber  
273 Name Withheld  
274 Name Withheld  
275 Name Withheld  
276 Coalition of Asia Pacific Tobacco Harm Reduction Advocates  
277 Vaping Association of Australia  
278 MOHRE  
279 Mr George Constantine  
280 Mr Craig Shillington  
281 P.T. Organisations Pty Ltd

**Additional Information**

- 1 Additional information provided by the Alcohol and Drug Foundation in relation to public hearing appearance on 2 May 2024; received 3 May 2024
- 2 Additional information provided by Associate Professor Michelle Jongenelis and Abby Robinson in relation to public hearing appearance on 2 May 2024; received 3 May 2024
- 3 Additional information provided by Associate Professor Michelle Jongenelis in relation to public hearing appearance on 2 May 2024; received 3 May 2024
- 4 Additional information provided by Liber Pharmaceutical in response to adverse comment by Vape4life made at a public hearing appearance on 2 May 2024; received 7 May 2024

**Answer to Question on Notice**

- 1 Answers to questions taken on notice by the Australian Council on Smoking and Health at a public hearing on 1 May 2024; received 6 May 2024.
- 2 Answers to questions taken on notice by the Australian Medical Association at a public hearing on 1 May 2024; received 6 May 2024.
- 3 Answers to questions taken on notice by Liber Pharmaceuticals at a public hearing on 1 May 2024; received 6 May 2024.
- 4 Answer to questions taken on notice by Dr Sandro Demaio at a public hearing on 1 May 2024; received 6 May 2024.
- 5 Answer to questions taken on notice by Professor Emily Banks at a public hearing on 1 May 2024; received 6 May 2024.
- 6 Answers to questions taken on notice by Professor Maree Teesson at a public hearing on 1 May 2024; received 6 May 2024.
- 7 Answers to questions taken on notice by the Royal Australian College of General Practitioners at a public hearing on 1 May 2024; received 7 May 2024.
- 8 Answers to questions taken on notice by Associate Professor Becky Freeman at a public hearing on 1 May 2024; received 6 May 2024.
- 9 Answer to questions taken on notice by Associate Professor Raglan Maddox at a public hearing on 1 May 2024; received 5 May 2024.
- 10 Answers to questions taken on notice by the Cancer Council, Heart Foundation, and Lung Foundation Australia at a public hearing on 1 May 2024; received 6 May 2024.
- 11 Answer to questions taken on notice by Emeritus Professor Simon Chapman AO at a public hearing on 1 May 2024; received 5 May 2024.
- 12 Answer to questions taken on notice by Lung Foundation Australia at a public hearing on 1 May 2024; received 6 May 2024.
- 13 Answer to questions taken on notice by Heart Foundation at a public hearing on 1 May 2024; received 6 May 2024.
- 14 Answer to questions taken on notice by Professor Tom Calma AO at a public hearing on 1 May 2024; received 6 May 2024.



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- 15 Answers to questions taken on notice by Associate Professor Michelle Jongenelis at a public hearing on 1 May 2024; received 6 May 2024.
  - 16 Answers to questions taken on notice by National Centre for Youth Substance Research at a public hearing on 1 May 2024; received 3 May 2024.
  - 17 Answers to questions taken on notice by Professor Ron Borland at a public hearing on 1 May 2024; received 3 May 2024.
  - 18 Answers to questions taken on notice by the Australian Border Force at a public hearing on 2 May 2024; received 6 May 2024.
  - 19 Answer to questions taken on notice by the Australian Secondary Principals Association at a public hearing on 2 May 2024; received 6 May 2024.
  - 20 Answers to questions taken on notice by Australian Parents Council at a public hearing on 2 May 2024; received 6 May 2024.
  - 21 Answers to questions taken on notice by Department of Health and Aged Care at a public hearing on 1 May 2024; received 6 May 2024.
  - 22 Answers to questions taken on notice by Professor Michael Farrell at a public hearing on 1 May 2024; received 8 May 2024.
  - 23 Answer to questions taken on notice by From the Fields Pharmaceutical at a public hearing on 1 May 2024; received 6 May 2024.
  - 24 Answer to questions taken on notice by Bay Pharma at a public hearing on 1 May 2024; received 8 May 2024.



# Appendix 2

## Public Hearings

*Wednesday, 1 May 2024*

Committee Room 2S1, Parliament House  
Canberra

*Cancer Council Australia*

- Professor Tanya Buchanan, Chief Executive Officer – via videoconference
- Ms Anita Dessaix, Director, Cancer Control Policy – via videoconference

*Lung Foundation Australia*

- Mr Mark Brooke, Chief Executive Officer – via videoconference

*National Heart Foundation of Australia*

- Professor Garry Jennings AO, Chief Medical Officer – via videoconference

*Cancer Australia*

- Ms Claire Howlett, Acting Chief Executive Officer and Deputy Chief Executive Officer
- Professor Vivienne Milch, Medical Director and Head, Clinical Policy Advice Branch

*Australian Medical Association*

- Dr Michael Bonning, Chair, AMA Public Health Committee
- Professor Stephen Robson, Federal President – via teleconference

*Royal Australia New Zealand College of General Practitioners*

- Professor Rowena Ivers, Member RACGP Quality Committee, Expert Advisory Committee on Tobacco

*Bay Pharma*

- Mr David Burns, Director, Sales and Marketing

*Liber Pharmaceuticals*

- Mr Richard Lee, Chief Executive Officer

*From the Fields Pharmaceutical*

- Mr Wilhelm David, Chief Executive Officer and Co-Founder

*Professor Tom Calma AO, Private capacity – via videoconference*

*Associate Professor Raglan Maddox – via videoconference*

*Dr Sandro Demaio, Chief Executive Officer, Victorian Health Promotion Foundation*

*Professor Emily Banks AM, Private capacity*

*Associate Professor Becky Freeman, Private capacity*

*Associate Professor Michelle Jongenelis, Private capacity*

*Professor Ron Borland, Private capacity – via videoconference*

*Professor Michael Farrell, Private capacity*

*Emeritus Professor Simon Chapman AO, Private capacity – via videoconference*

*Professor Matthew Peters, Private capacity – via videoconference*

*Australian Council on Smoking and Health*

- Ms Laura Hunter, Co-Chief Executive Officer – via videoconference
- Professor André Schultz, President – via videoconference

*National Centre for Youth Substance Use Research*

- Professor Jason Connor, Director – via videoconference
- Associate Professor Gary Chan – via videoconference
- Ms Tianze Sun, Postdoctoral Research Fellow – via videoconference
- Ms Giang Vu, PhD Scholar – via videoconference

*Associate Professor Emily Stockings, Private capacity*

*Professor Maree Teesson, Private capacity*

### ***Thursday, 2 May 2024***

Committee Room 2S1, Parliament House  
Canberra

*Australian Council of State School Organisations*

- Mr Damien Ellwood, President
- Mrs Dianne Giblin, Chief Executive Officer

*Kidsafe WA*

- Mr Scott Phillips, Chief Executive Officer – via videoconference

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*Australian Parents Council*

- Mrs Jenny Branch-Allen, President – via videoconference

*Alcohol and Drug Foundation*

- Dr Erin Lalor, Chief Executive Officer
- Mr Robert Taylor, Manager, Policy and Engagement

*Australian Alcohol & Other Drugs Council*

- Ms Melanie Walker, Chief Executive Officer
- Mr James Dunne, Policy and Projects Coordinator

*Dr Colin Mendelsohn, Private capacity – via videoconference*

*Panel of Independent Vaping Store Owners*

- The Vape Store – Ms Jacqueline Munn – via videoconference
- Vape4life – Mr Craig Jackman – via videoconference
- Flavourhype Distribution – Mr Greg Isaacs – via videoconference

*Vaping Consumer*

- Mr Justin Leary, Private capacity – via videoconference

*Police Federation of Australia*

- Mr Scott Weber, Chief Executive Officer – via videoconference

*Dr James Martin, Private capacity*

*Dr Alex Wodak, Private capacity – via videoconference*

*Australian Secondary Principals' Association*

- Mr Andy Mison, President – via videoconference

*Australian Border Force*

- Mr Michael Outram, Commissioner
- Mr Tim Fitzgerald, Deputy Commissioner

*National Vaping Working Group*

- Ms Susan Pearce, Co-Chair, and Secretary of NSW Health – via videoconference

*Australian Federal Police*

- Ms Kirsty Schofield, Assistant Commissioner

*Department of Health and Aged Care*

- Professor Anothony Lawler, Deputy Secretary, Health Products Regulation Group
- Dr Bridget Gilmour-Walsh, Principal Legal and Policy Adviser, Health Products Regulation Group

- Mr Chris Bedford, Acting First Assistant Secretary, Regulatory Practice & Support Division
- Mrs Tiali Goodchild, Acting First Assistant Secretary, Population Health Division
- Ms Karlie Brown, Assistant Secretary Tobacco and E-Cigarette Control Branch
- Ms Mandy Edlington, Acting Assistant Secretary, Vaping Legislative Reform Branch
- Mrs Jodie Grieve, First Assistant Secretary, People, Communication and Parliamentary Branch