



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Proposal to prevent the uptake of nicotine containing e-cigarettes by ever users (adolescents and young adults), to support smoking cessation and to reduce nicotine poisonings of children

Regulation Impact Statement for the Secretary of the Department of Health and his delegate including when acting under s52D(2) of the *Therapeutic Goods Act 1989*

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**TGA** Health Safety  
Regulation

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# Executive Summary

## The public health problem

1. Within Australia and internationally there is widespread concern particularly among public health policy makers and practitioners at the increased use of e-cigarettes containing nicotine in solution or salt or base form particularly by youth. Accidental poisonings of children by consumption of nicotine from e-liquid refills is also worrying.
2. The Australian Institute of Health and Welfare's (AIHW) National Drug Strategy Household Survey 2019 reported that e-cigarette usage has significantly increased for both smokers and non-smokers between 2016 and 2019.<sup>1</sup> There has also been a large increase in the use of e-cigarettes, particularly in the 14-18, 18-24 and 25-29 year age groups, with a 2-4 fold increase during that time period.<sup>2</sup> The trajectory for this cohort is concerning, with adequate warning of the potential Australian future from the exponential increase in use by US High Schools; in 2019 27.5 % are current e-cigarette users up from 11.7% in 2017 and by Canadians aged 15-19 - 15 % are current e-cigarette users in 2019 up from 6% in 2017. The US Surgeon General described the circumstances in the US as an 'epidemic of youth e-cigarette use'.<sup>3</sup>
3. Strong evidence of both nicotine e-cigarettes acting as a 'gateway' to smoking in youth and that exposure to nicotine in adolescents may have long-term consequences for brain development, sounds an even more ominous warning for public health policy makers including the Department.
4. There are also risks to public health of the use of nicotine containing e-cigarettes including the direct toxic effects of nicotine (and other e-cigarette components) to the nervous, cardiovascular and respiratory systems; of addiction (nicotine is highly addictive like heroin

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1. <sup>1</sup> The AIHW (<https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents>) characterises past and present cigarette users according to the following criteria:

- Daily smoker:
  - Reported smoking tobacco at least once a day (includes manufactured (packet) cigarettes, roll-your-own cigarettes, cigars or pipes). Excludes chewing tobacco, electronic cigarettes (and similar) and smoking of non-tobacco products.
- Ex-smoker:
  - Smoked at least 100 cigarettes or equivalent tobacco in their lifetime but does not smoke at all now.
- Never smoker:
  - Does not smoke now and has never smoked more than 100 cigarettes in their lifetime.
- Ever user:
  - A person who has used at least once in lifetime.<sup>1</sup> These terms will be referred to throughout the RIS.

<sup>2</sup> <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents>.

<sup>3</sup> [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/surgeon-general-advisory/index.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html)

and cocaine<sup>4</sup>). Nicotine exposure in adolescents not only harms brain development, it also impacts learning, memory and attention and increases the risk for future addiction to other drugs. There is a risk of poisoning (including deaths) of young children through consumption of nicotine e-cigarette fluids.

5. At the same time, the cost to Australian smokers, their loved ones and the public health system of tobacco use is profound. Tobacco use remains a leading cause of preventable death and disability in Australia and was estimated to kill almost 21,000 Australians in 2015.<sup>23</sup> Tobacco use compounds health and social inequalities and is a major contributor to poorer health status in socioeconomically disadvantaged populations.
6. The most recent available estimates of the overall social (including health) costs of tobacco use in Australia were \$137 billion in 2015-16. This included \$19.2 billion in tangible costs and \$117.7 billion in intangible costs.<sup>5</sup>
7. Tangible costs included health care costs (\$6.8 billion), workplace costs (\$5 billion), costs related to premature deaths (\$1.8 billion) and other costs primarily associated with fires, litter and expenditure on tobacco by dependent smokers (\$5.7 billion). In addition to the tangible costs of smoking, there are substantial intangible costs (e.g. the value of life lost, pain and suffering), both from premature mortality (\$92.1 billion) and from the lost quality of life of those experiencing smoking attributable ill-health (\$25.6 billion).<sup>6</sup>
8. With such statistics and with some promising evidence that nicotine containing e-cigarettes are a way to quit smoking, they are often marketed for this purpose. Presently, however, there is limited and highly contested clinically supported evidence of e-cigarettes being efficacious as a tool for durable smoking cessation.
9. There are no Therapeutic Goods Administration (the TGA) approved e-cigarettes for sale to help people quit smoking.
10. With this state of evidence, as stewards of public health, the Australian Government as well as state and territory governments are taking a precautionary approach to e-cigarettes; this approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation.
11. Because the public health concern is with nicotine containing e-cigarettes this regulatory impact statement is concerned with regulation of nicotine and e-cigarettes containing nicotine. It does not address *broader* risks and harms associated with smoking itself or non-nicotine e-cigarettes. It advises the Department on the options available to it to respond to the state of evidence of risks to public health from the use of nicotine containing e-cigarettes

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<sup>4</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>5</sup> Tait R, Whetton S and Alsop S. Identifying the social costs of tobacco use in Australia in 2015/16. Perth: National Drug Research Institute, Curtin University; October 2019. Available from: <https://ndri.curtin.edu.au/ndri/media/documents/publications/T273.pdf>.

<sup>6</sup> Ibid

simultaneously with addressing their increased use. In this regard, however, it is accepted that whether e-cigarettes contain nicotine or they do not, they will inevitably also include other chemicals, at least propylene glycol and vegetable glycerine and, generally, flavourings. The RIS would therefore be incomplete without some commentary on the impact of these additional ingredients. This does not equate to making any argument for the regulation of non-nicotine containing e-cigarettes.

12. Wherever possible correct references to nicotine containing e-cigarettes are made. In many instances, however, this is not possible. To the extent that it is impossible to do so, the observations made arguably remain relevant at least insofar as it is reasonable to assume that it is the inclusion of nicotine which drives their use and the associated risk. The conclusions from the US and the NSW Ministry of Health referred to at paragraph [71] of the high proportion of e-cigarettes containing nicotine, even when they are not labelled as such, also suggest that this is prudent.
13. The Department's three key public health objectives, along with the reasons behind the prevalence of use of nicotine containing e-cigarettes, formulate the response.

## **The objectives of the Department's action**

14. The objectives of the Department's action are to:
  - arrest the recent rapid increase in use of nicotine containing e-cigarettes by ever users, particularly adolescents and young adults;
  - provide to patients who want to stop smoking efficacious support, not already available (such as the Quit program) - likely in the form of medical practitioner support, including considering whether to prescribe nicotine containing e-cigarettes; and
  - reduce the likelihood of child poisoning by accidental consumption of nicotine.

## **The appropriate regulatory response is a function of the cause of the problem**

15. The appropriate regulatory response to deliver on these objectives is a function of the cause of the problem the Department is trying to solve (the uncertain impact on public health of use of nicotine containing e-cigarettes and their increased use in recent years).
16. Without discounting the possibility of domestic purchases of nicotine containing e-cigarettes, despite their sale being a criminal offence, it is widely accepted that the rapid increase in use of nicotine containing e-cigarettes including by adolescents and young adults has been a function of the ease with which the products may be purchased online from international retailers. This arises because of the current lacuna in regulation of nicotine containing e-cigarettes (and e-cigarette liquids) at the Commonwealth level relative to the states and territories.
17. It is illegal in every state and territory to sell e-cigarettes containing nicotine. However, there is no Commonwealth (importation) equivalent to the current state and territory prohibition on the sale of e-cigarettes containing nicotine; there is no effective



Commonwealth restriction on the importation of nicotine containing e-cigarettes and relevant refills ordered from overseas suppliers.

18. The absence of effective Commonwealth regulation of the importation of nicotine containing e-cigarettes is itself a function of the entries of nicotine in Schedules 4 and 7 of the Poisons Standard. Nicotine (excluding nicotine in tobacco and in specified nicotine replacement therapies) for human therapeutic use (as an aid to stop smoking) is in Schedule 4; nicotine (with the same exclusions for Schedule 4) for human use which is non-therapeutic (non-medical use) is in Schedule 7. A medicine containing a substance in Schedule 4 may only be lawfully supplied under state and territory law in accordance with a prescription. A good containing a substance in Schedule 7 substance is a dangerous poison for which generally state and territory law makes personal use or possession unlawful other than in South Australia.

19. It follows, therefore, that because:

- imports of nicotine for non-therapeutic use are not in Schedule 4 of the Poisons Standard, and
- the ‘personal importation scheme’ under the therapeutic goods framework:
  - i. does not exclude its use for the importation of a product including a Schedule 7 substance; and
  - ii. only requires a prescription to support the importation on medicines containing Schedule 4 substances; and
- the sale of nicotine containing e-cigarettes is unlawful in every state and territory

consumers have turned to importation (on a large scale) to purchase nicotine containing e-cigarettes. Anecdotally, the internet purchase from overseas suppliers is consumers preferred avenue of purchase. This is also despite their sale being prohibited in every state and territory and their use / possession being prohibited in every state and territory (other than South Australia).

20. It follows that there are no powers at present for the Australian Border Force to intercept these products at the border, and because these products are being shipped directly from the overseas company to the purchaser’s home, for internet purchases it is almost impossible for state and territory government agencies to police such purchase or use.

21. Present state and territory laws regulating nicotine containing e-cigarettes are, therefore, being undermined by:

- the failure to include nicotine for *all* human use in Schedule 4 of the Poisons Standard; and / or
- the absence of effective Commonwealth regulation of the importation of such products.

22. This regulatory lacuna also means that those purporting to use nicotine containing e-cigarettes as an aid to stop smoking have generally been without the support of a medical practitioner, arguably uniquely placed to give the support required to make appropriately

risk based health choices.<sup>7</sup> A patient’s doctor would work in partnership with his or her patient to take account of the patient’s physical and mental health, as well as use of medication, to advise on the most appropriate measure to aid smoking cessation – whether it be a prescription medicine, nicotine replacement therapy (NRT) or behavioural management.

23. On the basis of the problem, its root cause and the objective of the regulatory response there are four potential options explored in the regulation impact statement (RIS) as set out in Table 1:

**Table 1: Key options explored in the RIS to fill the regulatory lacuna**

Option	Elements
<b>Option 1</b>	Maintain the status quo (no change)
<b>Option 2</b>	Public awareness campaign - stop initiation / dependence on e-cigarette / smoking cessation
<b>Option 3</b>	Nicotine for all human use is included in the Poisons Standard as a prescription only medicine with a requirement for a child resistant closure for the container.
<b>Option 4</b>	Combination of options 2 and 3

## Recommended option

24. Option 1, the status quo, would fail to address the objectives of regulation, to balance the objectives of supporting smokers to stop smoking with protecting children and young people from risks associated with the use of nicotine containing e-cigarettes. The status quo also perpetuates the risk of nicotine poisoning of young children. Accordingly, the status quo is given no further consideration.
25. Option 2, a public awareness campaign, would address the *outcome* of the root cause of the problem – the regulatory lacuna between Commonwealth and state and territory law. Evidence of past smoking cessation education campaigns and the lapse of time since the last such campaign in 2012 means it is likely to have some success.

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<sup>7</sup> Stead LF, Buitrago D, Preciado N, Sanchez G, Hartmann-Boyce J, et al. Physician advice for smoking cessation. Cochrane Database of Systematic Reviews, 2013 DOI: 10.1002/14651858.CD000165.pub4, available from: <http://dx.doi.org/10.1002/14651858.CD000165.pub3>; Hall K, Kisely S, and Urrego F; The use of paediatrician interventions to increase smoking cessation counselling among smoking caregivers: A systematic review. Clinical Paediatrics, 2016, available from <http://www.ncbi.nlm.nih.gov/pubmed/26928569>; Hall K, Kisely S, and Urrego F. The use of pediatrician interventions to increase smoking cessation counseling among smoking caregivers: A systematic review. Clinical Pediatrics, 2016; US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

26. However, Option 2 would not address the underlying problem. Because the lack of information on the part of users of nicotine containing e-cigarettes is not the root cause of the problem but a symptom of it, a public awareness campaign is not likely the most appropriate response to the identified problem. This option also falls short of being the optimum that could be done to remove the risk of accidental nicotine poisoning of children.
27. Nevertheless, the absence of a regulatory burden associated with Option 2 as advised by Noetic Group (Noetic) has some attraction (see Noetic's Regulatory Burden Costings set out in Annexure D).
28. Considering the regulatory burden assessment of each option might suggest that Option 3, to include in Schedule 4 of the Poisons Standard nicotine for all human use so that it is a prescription only medicine with a requirement for a child resistant closure for the container, compares relatively poorly to Option 2. As follows, Noetic has assessed the total regulatory burden over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework) to be \$49,784,877:
- On adolescents and young adults to familiarise themselves with the regulatory changes (Noetic's assessment of the cost of familiarisation of all cohorts = \$630,355);
  - On e-cigarette users (at least monthly) to familiarise themselves with the regulatory changes (costing noted above), and for e-cigarette users (daily or weekly) to consult their medical practitioner (where they would not normally attend 2 such consultations per year) and, if prescribed nicotine containing e-cigarettes to fill the prescription (Noetic's assessment = \$48,273,417);
  - On medical practitioners to familiarise themselves with the regulatory changes, at least for the first year post the reform, to become an AP or to receive TGA approval for access under the SAS B scheme before prescribing nicotine containing e-cigarettes (Noetic's assessment = \$778,619);
  - On wholesalers to familiarise themselves with the regulatory changes (costing noted above); and
  - For a sponsor to apply to register a nicotine containing e-cigarette (Noetic's assessment = \$102,486).
29. Accordingly, the average annual regulatory burden over the 10-year regulatory period is \$4.98 million.
30. There are, however, good reasons in support of the view that Option 3 is preferable to Option 2. First, insofar as regulatory burden is concerned, it is notable that Option 3 poses no regulatory burden on any business engaged in the lawful retail of non-nicotine containing e-cigarettes and the relevant devices. This is because we understand that there is presently no interest from pharmacies in separately retailing e-liquid flavours to mix with nicotine and devices; current retailers of those products will continue to maintain their share of these markets. Of course, this says nothing about the preference of medical practitioners, working with their patients, to prescribe particular kinds of nicotine containing e-cigarettes – those which would require being refilled or pods. Such behaviour, driven by consumer preference with clinical judgement brought to bear, is intrinsically

linked to the usual forces which affect the development of any market. It is not possible, and therefore not appropriate, for the RIS to second guess what might prove to be the outcome. Sufficient demand by users for refillable e-cigarettes will ensure retailers maintain their current business model. The reasonably recent arrival of nicotine containing pods already threatens this business model.

31. Option 3 also creates an opportunity for others, notably medical wholesalers and pharmacies to supply nicotine containing e-cigarettes. It also creates an opportunity for a person, likely a business, to apply to register a product on the Australian Register of Therapeutic Goods (the ARTG).
32. Further, it is otherwise inappropriate to give any weight to any impact on sales which contravene state and territory laws prohibiting sales of nicotine containing e-cigarettes.
33. The second reason to prefer Option 3 is the degree to which it demonstrates its anticipated superior achievement in meeting the three regulatory objectives. Those objectives are set out at paragraph [14] and, briefly, are the 'on ramp' effect of arresting uptake of use of e-cigarettes in ever users, the 'off ramp' effect of providing support to smokers to quit and the reduction in accidental poisonings of children from consumption of nicotine e-liquids. This is the case, even accounting for smokers who may find the increased barriers to access to smoking cessation measures insurmountable; as well as for those ever users who may wish to risk commission of a criminal offence or contravention of a civil penalty provision and to continue to source nicotine containing e-cigarettes unlawfully.
34. Option 3 is structured to provide the most effective support to a smoker to stop smoking – that is the support from their medical practitioner.<sup>8</sup> Option 3 includes a clear barrier to access to nicotine containing e-cigarettes by ever users particularly adolescents and young adults – with the risk of commission of a criminal offence or civil penalty contravention posing a very strong deterrent to attempting access without a prescription. Option 3's inclusion of a requirement for all nicotine containing e-cigarettes to include a child resistant closure is the optimum measure to avoid accidental child poisonings by consumption of nicotine. This is appropriately the case in view of the vulnerability of this population and the risk of death.
35. Indeed, when appropriate consideration is given to the gravity of:
  - the evidence that tobacco use is associated with co-morbidities including that it remains a leading cause of preventable death and disability in Australia (estimating to kill 21,000 Australians in 2015) along with the present overall social (including health) costs of tobacco use in Australia estimated at \$137 billion in 2015-16;
  - the risk of the gateway effect on adolescents and young adults of use of e-cigarettes to smoking – that a whole new generation risks addiction to nicotine and smoking; and

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<sup>8</sup> Ibid

- the risk of accidental poisonings by children;

it is apparent that Option 3 is best placed to deliver on the identified regulatory objectives.

36. Option 4, a combination of options 2 and 3, would address the objectives of the regulation with the support of an appropriately targeted public awareness campaign and involve the same regulatory burden as Option 3. This would suggest possibly superior outcomes in terms of achieving the regulatory objectives.
37. The assessment of the possible superior outcome requires further consideration. Insofar as the benefit of the combination is concerned, it is likely that for the objectives of arresting 'on-ramp' uptake and eliminating nicotine poisoning of children, there is little to be gained by the public awareness campaign additional to the scheduling proposal. The requirement for a prescription, child resistant closure for a nicotine e-liquid container and engagement with a doctor on appropriate storage is likely, without more, to achieve the desired outcome.
38. A public awareness campaign targeted at smokers to quit would also achieve possible superior outcomes to Option 3 alone. It would incur a cost to the Budget in the range between \$10 million to \$40 million per annum, generating increasing degrees of success in encouraging smokers to quit with the increasing size of the investment (see paragraph [182]). On its face, it appears the preferable option.
39. For the smokers / non-smokers population, there is a need to pause and reflect, particularly on what weight should be given to the effect Options 3 would have of 'medicalising' nicotine containing e-cigarettes. The US Surgeon General states that 'Even brief (less than 3 minutes) advice from a physician improves cessation rates'<sup>9</sup> and is highly cost effective.<sup>10</sup> The 5As method is the gold standard for delivering this intervention, effective in increasing tobacco cessation and quit attempts among patients as well as increasing engagement in other empirically validated cessation treatments.<sup>11</sup> This method to intervention requires
- **Ask** - Identify and document tobacco use status for every patient at every visit.
  - **Advise** - In a clear, strong, and personalized manner, urge every tobacco user to quit.
  - **Assess** - Is the tobacco user willing to make a quit attempt at this time?
  - **Assist** - For the patient willing to make a quit attempt, use counselling and pharmacotherapy to help him or her quit.
  - **Arrange** - Schedule follow-up contact, in person or by telephone, preferably within the first week after the quit date.
40. That the most supportive measure for a person to quit, engagement with a medical practitioner, inheres in Option 3 suggests that whilst there is always more that might be

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<sup>9</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>10</sup> M V Maciosek, A LaFrance, S D Dehmer, D A McGree, T J Flottemesh, Z Xu, L Solberg, Updated priorities among effective clinical preventive services Ann Fam Med 2017 Jan; 15(1):14-22.

doi: 10.1370/afm.2017. Available from: <https://pubmed.ncbi.nlm.nih.gov/28376457/>

<sup>11</sup> Ibid

able to be achieved by additional measures, there is a questionable necessity for such measures. The question is even more pertinent when it is understood in the context of the addition of the 'What this means for you' education campaign to which the Department has committed in implementing Option 3 (see the explanation of the content of this education campaign at paragraph 259). On this basis, there is a not unreasonable argument for Option 3 to be allowed to run its course before designing and implementing other supplementary policies.

41. There is also a reasonable argument that longer term superior outcomes are likely if a public awareness campaign is designed with the benefit of the assessed impact of Option 3 (having launched with the benefit of the 'What this means for you' education campaign). That is, that it is reasonable for this to occur before determining the necessity for other measures; particularly those measures which require the allocation of scarce public health funds in the 2021-22 fiscal year..
42. Accordingly, pending an assessment of its impact at least 12 months after implementation, the preferred option is Option 3.
43. This Regulation Impact Statement (RIS) is intended to assist the Department to reach a decision, which would best promote the regulatory objectives.
44. It is only intended to assist the scheduling Delegate, to the extent that the considerations are consistent with the criteria ss 52D and 52E of the *Therapeutic Goods Act 1989* (the TG Act) and the *Therapeutic Goods Regulations 1990* (the TG Regulations) specify that the Delegate is required to take into account. In this regard, the decision of Jagot J in the matter of *Eve Hemp Pty Limited v Secretary to the Department of Health* [2017] FCA 1051, [31] is apposite. Her Honour held that 'in making a decision under s 52D(2) [of the TG Act] [the Delegate] must have regard to the matters in s 52E(1)<sup>12</sup> and *may* have regard to matters within the subject matter, scope and purpose of Part 6-3 of the TG Act construed in context (emphasis added).' As set out in s 52AA, the interests of public health and safety are central to the scope and purpose of that Part:

This Part provides the basis for a uniform system in Australia of access controls for goods containing scheduled substances.

The scheduling of substances allows restrictions to be placed on their supply to the public, *in the interests of public health and safety*. This is aimed at minimising the risks of poisoning from, and the misuse and abuse of, scheduled substances (emphasis added).

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<sup>12</sup> See further paragraph [324] of Annexure B.

## Introduction

### What is nicotine?

45. Nicotine is a liquid alkaloid obtained from the dried leaves of the tobacco plant, *Nicotiana tabacum* and related species (Solanaceae). Tobacco leaves contain 0.5 to 8% of nicotine as malate or citrate.
46. When smoked, nicotine is distilled from burning tobacco and carried on tar droplets (particulate matter), which are inhaled. Nicotine has a plasma half-life of approximately 2 hours. It is metabolised in the liver primarily by the CYP2A6 enzyme into cotinine which is excreted by the kidneys. Nicotine used in nicotine solutions for e-cigarettes is extracted from tobacco leaves.
47. On inhalation, the nicotine is rapidly absorbed into the blood and starts affecting the brain within 10 seconds. Once there, nicotine triggers a number of chemical reactions that create temporary feelings of pleasure and concentration. Some may also enjoy that nicotine curbs appetite and may contribute to weight loss.

### What is an e-cigarette?

48. The Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers conducted by the Australian House of Representatives Standing Committee on Health, Aged Care and Sport explains the development of the e-cigarette<sup>13</sup>:

*In 2003,<sup>14</sup> the electronic cigarette (E-cigarette) was developed by the Chinese pharmacist Hon Lik, who was struggling to quit smoking and wanted to develop a machine that could provide nicotine in a way that would mimic the 'look, feel and hit of smoking.'<sup>15</sup> In 2004, the first commercial release of E-cigarettes took place in China and, by 2007, E-cigarettes had started to appear in the United Kingdom of Great Britain (UK).<sup>16</sup>*

*E-cigarettes use battery power to heat a liquid (known as E-liquid) and disperse an aerosol solution which is inhaled by the user.<sup>17</sup> While technically an aerosol, the solution inhaled by the user is typically referred to as a vapour and this is the basis of the established terminology of E-cigarette use as 'vaping', and E-cigarette users as 'vapers'.<sup>18</sup>*

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<sup>13</sup> Parliament of Australia, "List of Recommendations", [https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25236](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25236)

<sup>14</sup> Ms Sarah Boseley, 'Hon Lik invented the E-cigarette to quit smoking – but now he's a dual user', *The Guardian*, 10 June 2015, <https://www.theguardian.com/society/2015/jun/09/hon-lik-e-cigarette-inventor-quit-smoking-dual-user>, Accessed 22 January 2018.

<sup>15</sup> Dr Alexander (Alex) David Wodak, President, Australian Drug Law Reform Foundation (ADLRF), *Official Committee Hansard*, Sydney, 12 July 2017, p. 9.

<sup>16</sup> Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

<sup>17</sup> Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

<sup>18</sup> Public Health England, *Exhibit 1: E-cigarettes: An Evidence Update*, p. 15.

*E-liquids may, but do not necessarily, contain nicotine. In addition, E-liquids typically contain food flavouring, propylene glycol, and vegetable glycerine.<sup>19</sup>*

**Figure 1.1: The evolution of e-cigarette, or vaping, products**



The four generations of e-cigarette products are, from left to right, (1) disposable e-cigarette, (2) e-cigarette with pre-filled or refillable cartridge, (3) tanks or mods (refillable), and (4) pod mods (pre-filled or refillable), the anatomy for which is at figure 1.4. Newer versions of e-cigarettes use nicotine salts which allow high levels of nicotine to be inhaled relatively easily with less throat irritation than earlier versions.

Source: Centers for Disease Control and Prevention – E-cigarette, or Vaping, Products Visual Dictionary; [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf)

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<sup>19</sup> Mr Savvas Dimitriou, Chairperson, Australian Vaping Advocacy, Trade and Research Inc (AVATAR), *Official Committee Hansard*, Melbourne, 5 October 2017, p. 40.



**Figure 1.2: E-cigarette products confiscated from students by staff members or found on school grounds — 16 high schools, California, 2018–19 academic year**



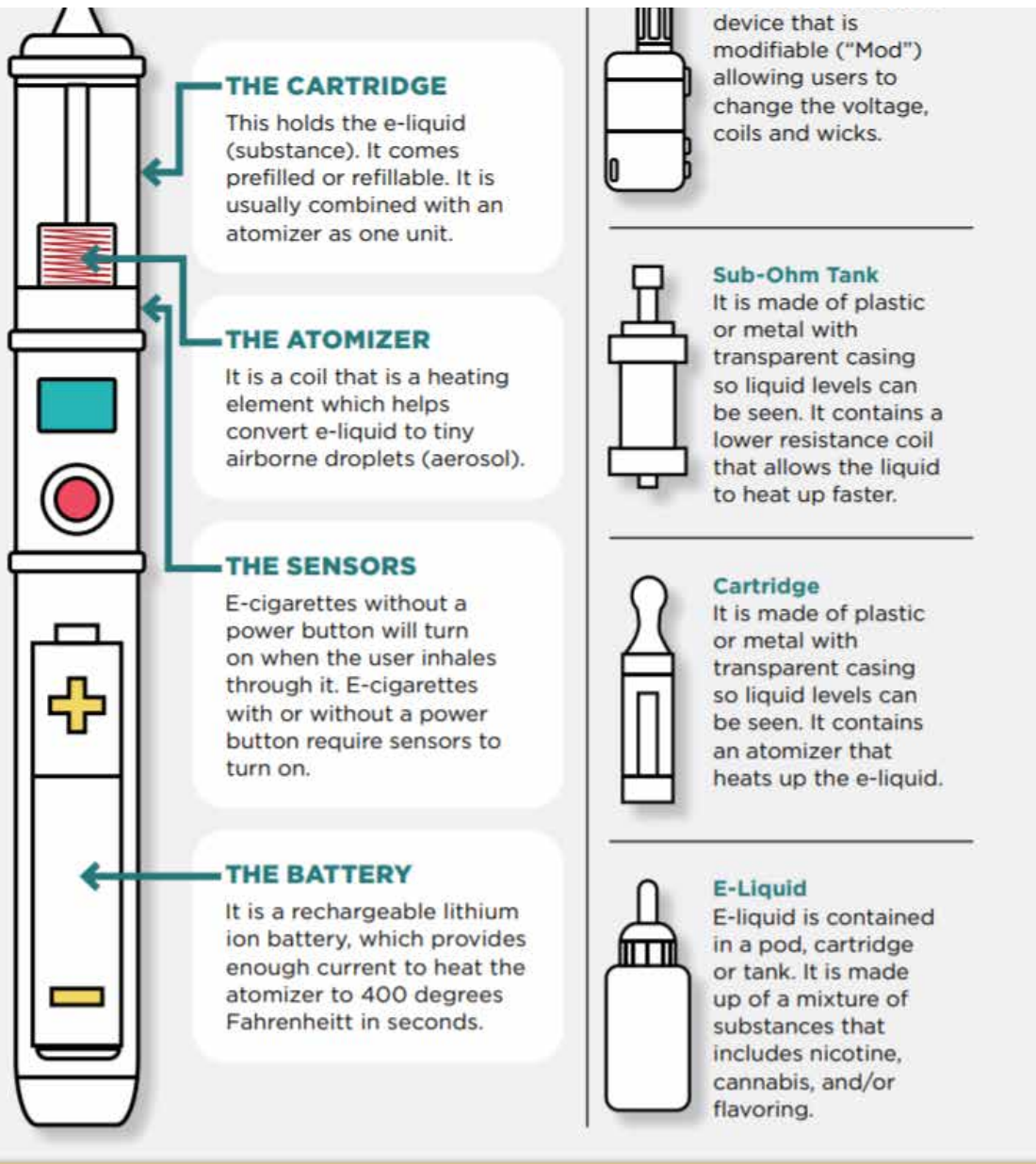
An image of 233 devices and 343 e-liquid cartridges collected in 16 Californian public high schools (1% of the total schools), a March 2019 Centers for Disease Control environmental assessment of products confiscated from students or found on school grounds.<sup>20</sup>

Source: California Department of Health and Department of Education;  
<https://www.cdc.gov/mmwr/volumes/69/wr/mm6942a7.htm>

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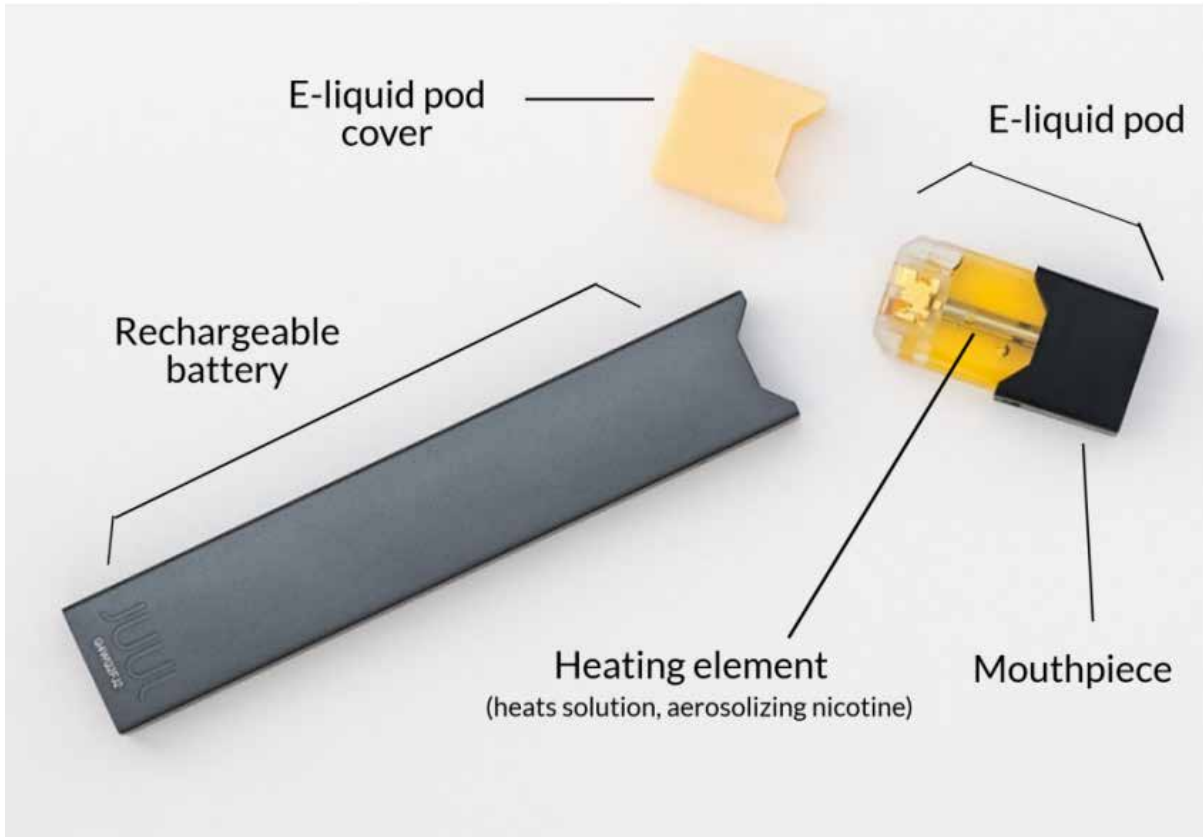
<sup>20</sup> Shamout M, Tansz, Herzig C, Oakley L, Peak C, Heinzerling A, Hast M, McGowan E, Williams R, Hess C, Wang C, Planche S, Herndon S, Martin J, Kansagra S, Al-Shawaf M, Melstrom P, Marynak K, Tynan M, Agaku T, King B A, Characteristics of E-cigarette, or Vaping, Products Confiscated in Public High Schools in California and North California – March and May 2019 available here  
<file:///U:/Documents/Characteristics%20of%20E-cigarette%20or%20Vaping%20Products%20confiscated%20in%20public%20high%20schools%20in%20California%20and%20North%20Carolina%20-%20March%20and%20May%202019.pdf>

Figure 1.3: Anatomy of an E-Cigarette – from 1<sup>st</sup> to 3<sup>rd</sup> generation



<sup>21</sup> [E-cigarette, or vaping, products visual dictionary](#), the US Department of Health and Human Services, Centers for Disease Control and Prevention, accessed 8 September 2020:

**Figure 1.4: Anatomy of an E-Cigarette – 4<sup>th</sup> generation**



Source: <https://www.kingcounty.gov/depts/health/tobacco/data/e-cigarettes.aspx>

## What is the regulatory context?

49. In its Report on the Global Tobacco Epidemic (2019)<sup>22</sup> the World Health Organization (WHO) recommended that Member States that have not banned Electronic Nicotine Delivery Systems (ENDS, i.e. nicotine containing e-cigarettes) should consider regulating them as harmful products, and governments should implement the regulatory measures for ENDS that they determine are most appropriate for their domestic context.
50. In 2018, the Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers conducted by the Australian House of Representatives Standing Committee on Health, Aged Care and Sport in March 2018 recommended that:
- The TGA continue to oversee the classification of nicotine and relevant exemptions, and the assessment of any electronic cigarette product as a therapeutic good (Recommendation 4); and
  - The Australian Government establish a regulatory process for assessing and, if necessary, restricting colourings and flavourings used in electronic cigarettes (Recommendation 5).<sup>23</sup>
51. In November 2019, the Ministerial Drug and Alcohol Forum endorsed a precautionary approach towards the regulation of e-cigarettes in Australia and outlined this in a set of principles that seek to underpin the current policy and regulatory approach.<sup>24</sup> The first principle includes protecting the health of children and young people and this is a key driver for regulatory reform in Australia.
52. The Senate Select Committee on Tobacco Harm Reduction, established on 6 October 2020, is inquiring into tobacco reduction strategies and is due to report on 18 December 2020.<sup>25</sup>
53. All Australian governments are taking a precautionary approach to e-cigarettes. This encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy.

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<sup>22</sup> WHO, "WHO report on the global tobacco epidemic 2019", [https://www.who.int/tobacco/global\\_report/en/](https://www.who.int/tobacco/global_report/en/), accessed 15 April 2020.

<sup>23</sup> Parliament of Australia, "List of Recommendations", [https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25236](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25236), Recommendation 3, accessed 15 April 2020.

<sup>24</sup> Department of Health, "Policy and Regulatory Approaches to electronic cigarettes (e-cigarettes) in Australia", 28 November 2019, <https://www.health.gov.au/sites/default/files/documents/2019/12/policy-and-regulatory-approach-to-electronic-cigarettes-e-cigarettes-in-australia-principles-that-underpin-the-current-policy-and-regulatory-approach-to-electronic-cigarettes-e-cigarettes-in-australia.pdf>.

<sup>25</sup> Senate Select Committee on Tobacco Harm Reduction, [https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Tobacco\\_Harm\\_Reduction/TobaccoHarmReduction](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Tobacco_Harm_Reduction/TobaccoHarmReduction)

54. On 27 February 2020, the Senate passed a motion<sup>26</sup> calling on the Government to ban the importation of e-cigarette liquids containing nicotine’ as well as for regulation of ‘the manufacture and labelling of e-cigarette liquid to ensure safety and consistency of ingredients in imported and domestically-available products’.

## Current regulation of nicotine

55. As discussed in some detail in Annexures B and C, the regulation of nicotine containing e-cigarettes is a shared responsibility between the federal and state and territory governments.

56. Regulation by Commonwealth law is a function of the use to which the e-cigarette containing nicotine is put:

- When used for smoking cessation purposes (that is for a therapeutic use), it is a prescription only medicine and may only be imported lawfully in accordance with the requirements of the Commonwealth therapeutic goods regulatory framework, if supported by a prescription; and
- When used for non-therapeutic ‘recreational use’, its import is not regulated by Commonwealth law.

57. On the other hand, in each state and territory it is illegal to sell nicotine containing e-cigarettes. Further, when used for non-medical ‘recreational’ purposes, possession or use of nicotine containing e-cigarettes is illegal in every state and territory other than South Australia.

58. These outcomes at both levels of government are a function of how nicotine appears in the Poisons Standard – as a prescription only medicine (Schedule 4 of the Poisons Standard) when used to aid smoking cessation and as a dangerous poison (Schedule 7 of the Poisons Standard) when used for a non-medical ‘recreational’ purpose.

**Table 2: Access schemes for nicotine-containing e-cigarettes for therapeutic and non-medical uses under current Poisons Standard**

NICOTINE-CONTAINING E-CIGARETTES FOR HUMAN USE		
Intended use	Therapeutic (Schedule 4)	Non-medical (Schedule 7)
Mode of access	Nicotine-containing e-cigarettes are a medicine to aid smoking cessation, available by prescription only	Nicotine-containing e-cigarettes are dangerous poisons, not available for lawful use

<sup>26</sup> Motion e-Cigarettes Products Senator Griff:

[https://parlinfo.aph.gov.au/parlInfo/download/chamber/hansards/7123b722-738a-4e51-9256-2815f1b3d2bd/toc\\_pdf/Senate\\_2020\\_02\\_27\\_7565\\_Official.pdf;fileType=application%2Fpdf](https://parlinfo.aph.gov.au/parlInfo/download/chamber/hansards/7123b722-738a-4e51-9256-2815f1b3d2bd/toc_pdf/Senate_2020_02_27_7565_Official.pdf;fileType=application%2Fpdf) accessed 8 September 2020

<b>NICOTINE-CONTAINING E-CIGARETTES FOR HUMAN USE</b>		
	Obtain prescription from medical practitioner	Purchase products from overseas supplier
<b>Safeguards</b>	Patient must be smoker, intending to quit	NA
<b>Importation and use</b>	Lawful import	Import not regulated by Commonwealth law
	Lawful purchase from pharmacist	Unlawful domestic purchase
	Lawful possession and use	Unlawful possession and use (except in S.A, see Annexure C)

59. With no powers at present for the Australian Border Force to intercept these products at the border and because these products are being shipped directly from the overseas company to the purchaser's home, for internet purchases it is almost impossible for state and territory government agencies to police such purchase or use.
60. Consumers have therefore turned to importation (on a large scale) to purchase nicotine containing e-cigarettes for 'non-medical' use. Anecdotally, the internet purchase from overseas suppliers is consumers preferred avenue of purchase. It is a relatively easy exercise to order e-cigarettes from an online retailer, the five most popular of which, in order of volume of sales, are Vapoaustralia, Vapoureyes, Vaporfi, Vapeking and Supervapestore, all hosted in Australia, other than Vaporfi.
61. The regulatory lacuna between Commonwealth and state and territory law produces six relevant outcomes.
62. First, nicotine containing e-cigarettes is growing among 'ever' users, increasingly adolescents and young adults, and this demand is predominately supplied by way of importation.
63. Second, present state and territory laws regulating nicotine containing e-cigarettes are being undermined by:
- the failure to include nicotine for *all* human use in Schedule 4 of the Poisons Standard; and / or
  - the absence of effective Commonwealth regulation of the importation of such products.
64. The third consequence of the regulatory lacuna between Commonwealth and state and territory law is that those purporting to use nicotine containing e-cigarettes as an aid to stop smoking have generally been without the support of a medical practitioner, arguably uniquely placed to give the support required to make appropriately risk based health choices.

65. Fourth, and related to the third consequence, the regulatory lacuna between Commonwealth and state and territory law explains the fact that there are presently only 14 Australian medical practitioners known to prescribe nicotine containing e-cigarettes.
66. Fifth, it means that there has been little, if any, incentive for an applicant to apply to the TGA to register a nicotine containing e-cigarette on the ARTG. There is, presently, no e-cigarette containing nicotine, which has been tested by the TGA for quality, safety or efficacy.
67. Sixth, there is little or no evidence of the use of the other lawful means by which a person may access an 'unapproved' product as an aid to smoking cessation (with a prescription) as follows:
- TGA 'Special Access Scheme B' approval to a medical practitioner for an individual patient or TGA authority to a medical practitioner as an authorised prescriber for a class of patients;
  - personal importation of up to 3 months' supply for personal use; and
  - extemporaneously compounded by a pharmacist.

# The problem

## The Consumer problem

### Prevalence of e-cigarette use

68. There has been widespread expansion of e-cigarette use internationally, with considerable differences in prevalence across jurisdictions. Population prevalence of e-cigarette use is relatively low in countries with strict regulatory controls on e-cigarettes such as Australia.
69. Other countries with more lax regulatory controls tell a different story, notably among adolescents and young adults; in 2019 15% of Canadians, aged between 15 and 19 were current e-cigarette users, up from 6% in 2017; in 2019 the USA recorded 27.5% of high school students were current users, up from 11.7% in 2017.
70. Nevertheless, the Australian Institute of Health and Welfare's (AIHW's) National Drug Strategy Household Survey 2019 reported that the use of e-cigarettes has increased between 2016 and 2019 for both current smokers and non-smokers.<sup>27</sup>
71. Although the data is not specified to be exclusively on nicotine-containing e-cigarettes, it is assumed that the overwhelming majority of use of e-cigarettes containing nicotine. This follows from the April 2017 report of the US Centers for Disease Control and Prevention that ninety nine per cent of e-cigarettes sold contained nicotine. The New South Wales Ministry of Health also reports that about two thirds of products they tested in 2018 contained nicotine even where the labels indicated the absence of nicotine.
72. Some major findings of the AIHW's survey were:
- Ever e-cigarette use has increased to 11.3% in 2019 (up from 8.8% in 2016).
  - Frequency of e-cigarette use also increased, with 17.9% of people who had ever tried an e-cigarette using them at least monthly (up from 10.3% in 2016).
73. The increase in e-cigarette use was particularly notable among young adults.
- Between 2016 and 2019, the proportion of survey respondents aged 18-24 who reported using e-cigarettes, daily, weekly, monthly or less than monthly nearly doubled, from 2.3% in 2016 to 4.5% in 2019.
  - Between 2013 to 2019, the proportion of survey respondents aged 18-24 who reported using an e-cigarette at least once in their lifetime increased from 14.8% to 22.3% in 2019 (see Figure 1).<sup>28</sup>

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<sup>27</sup> <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents/table-of-contents>

<sup>28</sup> Caution should be used when interpreting this finding. Changes to the 2016 NDSHS questionnaire mean that 2016 and 2013 data are not fully comparable, however data may still be used to give an indication of the change in use of e-cigarette use between 2013 and 2016.



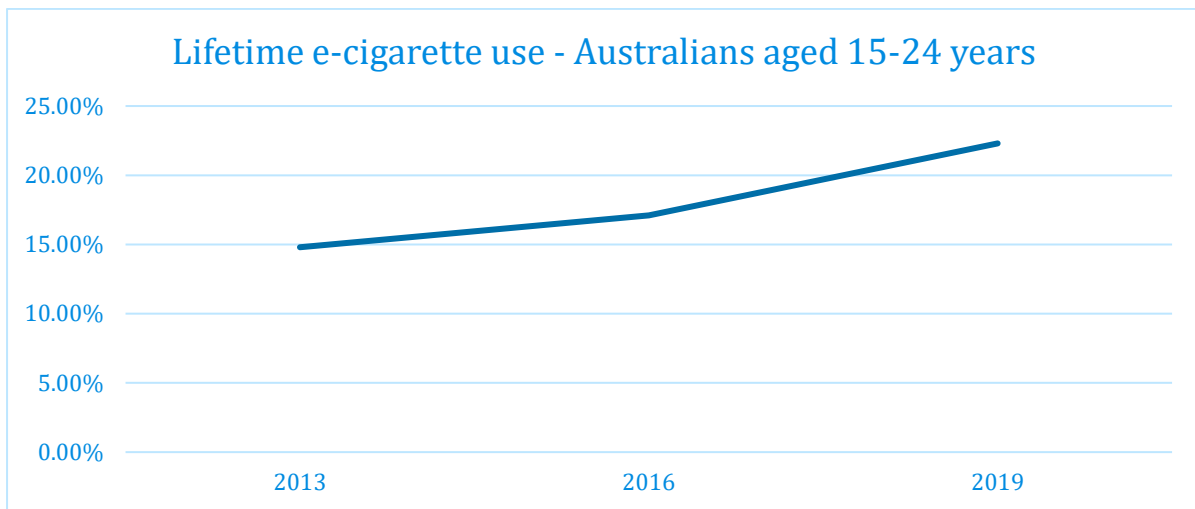
- Nearly 2 in 3 (64%) current smokers aged 18-24 reported ever trying e-cigarettes (up from 49% in 2016) and 18.7% used them at least monthly (up from 6.8% in 2016).
  - 1 in 5 (20%) non-smokers aged 18-24 reported having ever tried e-cigarettes.
74. There is concern that introducing youth to the use of e-cigarettes presents a gateway effect to cigarette use over a lifetime and / or risk of psychiatric disorders, future substance abuse and poor later life cognition.<sup>29</sup> The concern has only increased with the relatively recent publication of research lead by the National Centre for Epidemiology and Population Health at the Australian National University (the ANU)<sup>30</sup> and the Health Research Board (the HRB), a lead funding agency for health research in Ireland<sup>31</sup> (discussed further below under 'gateway effect' at paragraph [100]).
75. The frequency of e-cigarette use among smokers has increased.
- 9.7% of smokers reported ever using e-cigarettes (up from 4.4% in 2016).
  - Daily e-cigarette use among smokers increased to 3.2% in 2019 (up from 1.5% in 2016), and at least monthly use increased to 7.8% in 2019 (up from 3.4% in 2016).
76. 54% of people reported trying e-cigarettes out of curiosity. This was especially the case for never smokers (85%) and young adults aged 18-24 years (72%).
- 32% of people reported using e-cigarettes to help them quit smoking, similar to 31% in 2016.

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<sup>29</sup> Reported in Green M J, Lisay Grau, Sweeting H and Benzeval M Socioeconomic patterning of vaping by smoking status among UK adults and youth at <https://bmcpublikealth.biomedcentral.com/articles/10.1186/s12889-020-8270-3>; Grana RA. Electronic cigarettes: a new nicotine gateway? *J Adolesc Health*. 2013;52(2):135–6; Bell K, Keane H All gates lead to smoking: the 'gateway theory', e-cigarettes and the remaking of nicotine. *Soc Sci Med*. 2014;119:45–52; Leventhal AM, Strong DR, Kirkpatrick MG, et al. Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. *JAMA*. 2015;314(7):700–7; Treur JL, Rozema AD, Mathijssen JJ, et al. E-cigarette and waterpipe use in two adolescent cohorts: cross-sectional and longitudinal associations with conventional cigarette smoking. *Eur J Epidemiol*. 2018;33:323–34

<sup>30</sup> Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health, September 2020. Available at <http://hdl.handle.net/1885/211618>

<sup>31</sup> O'Brien D, Long J, Lee C, McCarthy A and Quigley J. Electronic cigarette use and tobacco cigarette smoking initiation in adolescents: An evidence review. Dublin: Health Research Board May 2020. Available from: [https://www.drugsandalcohol.ie/33170/1/Electronic\\_cigarette\\_use\\_and\\_smoking\\_initiation\\_in\\_adolescents.pdf](https://www.drugsandalcohol.ie/33170/1/Electronic_cigarette_use_and_smoking_initiation_in_adolescents.pdf).  
Electronic cigarette and smoking cessation. An evidence review. Available at <https://www.hrb.ie/publications/publication/electronic-cigarette-and-smoking-cessation-an-evidence-review/returnPage/1/>.  
Harms and benefits of e-cigarettes and heat-not-burn tobacco products. A literature map. Available at <https://www.hrb.ie/publications/publication/harms-and-benefits-of-e-cigarettes-and-heat-not-burn-tobacco-products-a-literature-map/>.

**Figure 1.5: Lifetime e-cigarette use among Australian youth between 2013 and 2019**

Source: National Drug Strategy Household Survey preliminary findings (2013-2019 Australian Data).

77. The consumer problem is also arguably affected by the information asymmetry on the possible costs to health of use of nicotine containing e-cigarettes. Although governments publically declare their agreement that they are taking a precautionary approach to the use of nicotine containing combustible cigarettes, their use is, nevertheless, widely promoted as less harmful to smoking. It is reasonable to assume that those profiting from their sales have an incentive to drown any public health and safety message.
78. There is also a sense that consumers have a right to unrestricted access to nicotine containing e-cigarettes because they have their own personal assessment of their health risks compared to the potential benefit to them from their use. This could also be compared to other consumers who consider it is their consumer right to consume other psychoactive substances for recreational purposes based on their own personal risk assessment.
79. Individual testimonies about the use of nicotine containing e-cigarettes to assist the user to quit smoking are inevitably heart felt and, in this sense, compelling. It is inappropriate to dismiss them. However, anecdotal reports of individuals who have quit smoking with the aid of nicotine containing e-cigarettes, as with data from one study alone, does not equate to the kind of evidence necessary for the kind of critical assessment of the harms and benefits of a proposed approach. The net costs and benefits of e-cigarette use must be assessed at the population level. Whilst the voice of the consumer is therefore necessarily a component part of the consumer story it does not foreclose the outcome.
80. Further, the costs of nicotine addiction and transitioning to smoking are largely met by public health expenditure supporting those affected by smoking affected illnesses. Tobacco use remains the leading risk factor for ill health and premature death in Australia, contributing to 21,000 deaths in Australia in 2015.<sup>32</sup> In this regard, the existence of the Poisons Standard demonstrates decades of acceptance that public regulation of control access to poisons in consideration of their detrimental effects at a community level even if

<sup>32</sup> [https://www.aihw.gov.au/news-media/media-releases/2019/october/tobacco-use-linked-to-more-than-1-in-8-deaths-but#:~:text=Tobacco%20use%20contributed%20to%20an,Health%20and%20Welfare%20\(AIHW\).](https://www.aihw.gov.au/news-media/media-releases/2019/october/tobacco-use-linked-to-more-than-1-in-8-deaths-but#:~:text=Tobacco%20use%20contributed%20to%20an,Health%20and%20Welfare%20(AIHW).)

that denies the individual consumer's right to consume them. One notable exception is the scheduling of nicotine prepared and packed for smoking which, from the inception of the Poisons Standard in 1955, was considered outside the scheduling framework.

## Profile of users of e-cigarettes

81. In addition to the increased prevalence of young people, using e-cigarettes there is some evidence of socioeconomic disadvantage associated with vaping among ever smoking youth and among ex-smoking adults with little or no association among ever smoking and current smoking adults.<sup>33</sup> Further, people within low socio-economic status segments have higher rates of smoking than those in more advantaged socio-economic status segments.<sup>34</sup>
82. E-cigarette use is significantly higher among people with depression, alcohol problems, severe obesity and cancer.<sup>35</sup> This is consistent with evidence that there is a much higher smoking prevalence rate among those with mental health disorders.<sup>36</sup> The Royal Australian and New Zealand College of Psychiatrists supports its observation of 'the disproportionately high smoking prevalence, and low quit rates, among people living with mental illness'<sup>37</sup>, by noting research in Australia demonstrating that 70% of people with schizophrenia and 61% of people with bipolar disorder smoke compared to, at that time, 16% of those without mental illness.<sup>38</sup> The College also notes research that people living with mental illness are not only more likely to smoke, but they also tend to smoke more heavily than the general population<sup>39</sup> and are less likely to succeed during a smoking cessation attempt.<sup>40</sup>
83. The daily smoking rate of Aboriginal and Torres Strait Islander peoples is almost three times that of non-Indigenous Australians. Twenty-three per cent of the health gap between

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<sup>33</sup> Green MJ, Gray L, Sweeting H, Benzeval M. Socioeconomic patterning of vaping by smoking status among UK adults and youth. *BMC Public Health* 2020; 20(1): 183

<sup>34</sup> Scollo M, Winstanley M. Tobacco in Australia: facts and issues. Melbourne: Cancer Council Victoria; 2019 [cited 2019 Nov 4]. Available from: [www.TobaccoInAustralia.org.au](http://www.TobaccoInAustralia.org.au) referred to in Beasley SJ, Barker A, Murphy M, Roderick T, Carroll T. What makes an effective antismoking campaign: insights from the trenches. *Public Health Res Pract.* 2020;30(3):e3032021. <https://doi.org/10.17061/phrp3032021>

<sup>35</sup> Li L, Borland R, O'Connor RJ, et al. How Are Self-Reported Physical and Mental Health Conditions Related to Vaping Activities among Smokers and Quitters: Findings from the ITC Four Country Smoking and Vaping Wave 1 Survey. *International journal of environmental research and public health* 2019; 16(8)

<sup>36</sup> Lawrence D, Mitrou F, Zubick SR Smoking and mental illness: Results from population surveys in Australia and in the United States *BMC Public Health* 2009.9.285.doi: 10.1186/1471-2458-9-285

<sup>37</sup> Royal Australian and New Zealand College of Psychiatrists Position Statement 97, E-cigarettes and Vaporiser at <https://www.ranzcp.org/news-policy/policy-and-advocacy/position-statements/e-cigarettes-and-vaporisers> accessed 20 October 2020.

<sup>38</sup> Cooper J, Mancuso SG, Borland R (2012) Tobacco smoking among people living with a psychotic illness: The second Australian Survey of Psychosis. *Australian and New Zealand Journal of Psychiatry* 46: 851–863.

<sup>39</sup> Ratschen E (2014) Electronic cigarettes in mental health settings – solving a conundrum? *British Journal Psychiatric Bulletin* 38(5): 226–9

<sup>40</sup> Cather C, Pachas GN, Cieslak KM, Evins AE (2017) Achieving Smoking Cessation in Individuals with Schizophrenia: Special Considerations. *CNS Drugs* 31(6): 471–81. doi: 10.1007/s40263-017-0438-8. PMID: 28550660. PMCID: PMC5646360. NIHMSID: NIHMS879908. PMID: 28550660

Aboriginal and Torres Strait Islander peoples and non-indigenous Australians is attributable to tobacco smoking.<sup>41</sup>

## Harm caused by e-cigarettes

84. There is growing evidence that e-cigarette products with and without nicotine pose a range of harms to human health. Evidence from observational and experimental studies has implicated the use of e-cigarettes in various harms to the heart and lungs.<sup>42</sup> Known carcinogens have also been found in e-cigarette aerosols, although the extent to which e-cigarette use increases the risk of cancer remains unknown.<sup>43</sup>
85. There is absence of information about the side effects of using nicotine containing e-cigarettes for more than 2 years.<sup>44</sup>
86. The wide variation in e-cigarette products and the ability of users to customise their experience also makes it difficult to assess the direct health harms of individual products because the results from research involving one particular product may not be applicable to all e-cigarettes or all users. For example, thousands of different flavouring compounds may be marketed and used with e-cigarette. However, while many flavouring compounds may be recognised as safe for use in food products, no flavouring product have been assessed as safe for inhalation via an e-cigarette.
87. Whilst it is accepted that *completely* switching to nicotine containing e-cigarettes from combustible cigarettes reduces exposure to toxicants and carcinogens,<sup>45</sup> the often cited claim that e-cigarettes are 95% less harmful than combustible cigarettes<sup>46</sup> has been challenged.<sup>47</sup> First, the '95% claim' emerges from the findings in July 2013 of a group of 12 experts in decision science, medicine, pharmacology, psychology, public health policy and toxicology rating the relative harm of 12 nicotine-containing products by 14 criteria concerned with harm to users and to others. The authors themselves acknowledged the absence of hard evidence for the harms of most of the products. Professor Nick Zwar,

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<sup>41</sup> AIHW Australian Burden of Disease Study: Impact and causes of illnesses and death in Aboriginal and Torres Strait Islander people 2011. Australian Burden of Disease Study series no. 6 Cat. No. BOD 7. Canberra ACT: AIHW.2016

<sup>42</sup> For example, see: Gotts et al. 2019. What are the respiratory effects of e-cigarettes? *BMJ*; 336:l5275 Available at: <https://www.bmj.com/content/366/bmj.l5275>

Kennedy et al 2019. The cardiovascular effects of electronic cigarettes: A systematic review of experimental studies. *Preventive Medicine*. Available at: <https://www.sciencedirect.com/science/article/pii/S0091743519302464>

Fetterman et al. 2020. Alterations in Vascular Function Associated With the Use of Combustible and Electronic Cigarettes. *Journal of the American Heart Association*. Available at: <https://www.ahajournals.org/doi/full/10.1161/JAHA.119.014570>

<sup>43</sup> Bozier et al. 2019. The Evolving Landscape of Electronic Cigarettes: A systematic review of recent evidence, CHEST. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/32006591>

<sup>44</sup> Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A et al. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2020; (10): CD010216. doi: 10.1002/14651858.CD010216.pub4.

<sup>45</sup> Morean ME, Krishnan-Sarin S, Sussman S, et al. Psychometric Evaluation of the E-cigarette Dependence Scale. *Nicotine Tob Res*. 2019;21(11):1556-1564 <https://doi.org/10.1093/ntr/ntx271>

<sup>46</sup> Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction available at <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

<sup>47</sup> Lancet Editorial Vol 386 August 29, 2015 and Eissenberg, A, Bhatnagar A, Chapman S, Jordt S E, Shihadeh A and Soule E K *American Journal of Public Health* February 2020 <https://dx.doi.org/10.2105%2FAJPH.2019.305424>

Executive Dean of Health Sciences and Medicine at Bond University has commented: ‘That’s a group of people sitting around and coming up with a figure. That is not data.’<sup>48</sup>

88. In their submission to the Senate Select Committee on Tobacco Harm Reduction Professors Tony Blakely and Nick Wilson and Doctors Jennifer Summers and Driss Ait Ouakrim from the Universities of Melbourne and Otago, reported on new evidence of toxicology studies on the impact of vaping on chronic lung disease, cardiovascular disease and cancers. They advised that their report that vaping had only 5% of the harm of smoked tobacco is no longer accurate.<sup>49</sup>
89. Further, e-cigarettes have changed considerably since that July 2013 study with today’s e-cigarettes attaining power output exceeding the 2013 models by 10 to 20 times and more concentrated liquids. Greater power exposes users to increased levels of nicotine and other toxicants. The increased range of flavours and chemicals (see the section following the next) also exposes users to unknown pulmonary toxicity. Use of nicotine salts (protonated nicotine made by adding an acid to free-base nicotine) has also meant that nicotine is available in greater concentrations.<sup>50</sup>
90. Again, although not limited to nicotine containing e-cigarettes it is not irrelevant to note that e-cigarettes also provide health risks to bystanders from exposure to exhaled aerosol from e-cigarette users. A recent systematic review of the health risks from second-hand e-cigarette aerosol concluded that ‘the absolute impact from passive exposure to electronic cigarette vapour has the potential to lead to adverse health effects’.<sup>51</sup>

### ***Risk of addiction***

91. There are significant risks associated with exposure to nicotine. It is highly addictive and there is a risk of nicotine dependence when used with e-cigarettes.<sup>52</sup>
92. Youth are uniquely susceptible to nicotine addiction with the addictive potential so high that the US Surgeon General has declared that youth use of nicotine in any form is unsafe.<sup>53</sup>

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<sup>48</sup> Referred to in ‘Blood in the water’: Why the next 12 months is critical for vaping regulation’ in October RACGP news available at <https://www1.racgp.org.au/newsgp/clinical/blood-in-the-water-why-the-next-12-months-is-critical>.

<sup>49</sup> Submission no. 405 -

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Tobacco\\_Harm\\_Reduction/TobaccoHarmReduction/Submissions](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Tobacco_Harm_Reduction/TobaccoHarmReduction/Submissions)

<sup>50</sup> Eissenberg, A, Bhatnagar A, Chapman S, Jordt S E, Shihadeh A and Soule E K American Journal of Public Health February 2020 <https://dx.doi.org/10.2105%2FAJPH.2019.305424>

<sup>51</sup> Hess IM, Lachireddy K and Capon A. A systematic review of the health risks from passive exposure to electronic cigarette vapour. Public Health Research and Practice 2016; 26(2): 2621617. doi: 10.17061/phrp2621617

<sup>52</sup> Jankowski M, Krzystanek M, Zejda J, Majek P, Lubanski J, Lawson J, Brozek G, E-cigarettes are more addictive than Traditional Cigarettes – A study in Highly Educated Young People Available from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6651627/>; Case K, Mantey D, Creamer, M, Harrell M, Kelder S, Perry C, E-cigarette specific symptoms of nicotine dependents among Texas adolescents available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6655516/>; Vogel E, Cho J, McConnel R, Barrington-Trimis J, Leventhal A, Prevalence of Electronic Cigarette Dependence Among Youth and Its Association With Future Use available, open access article.

<sup>53</sup> US Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

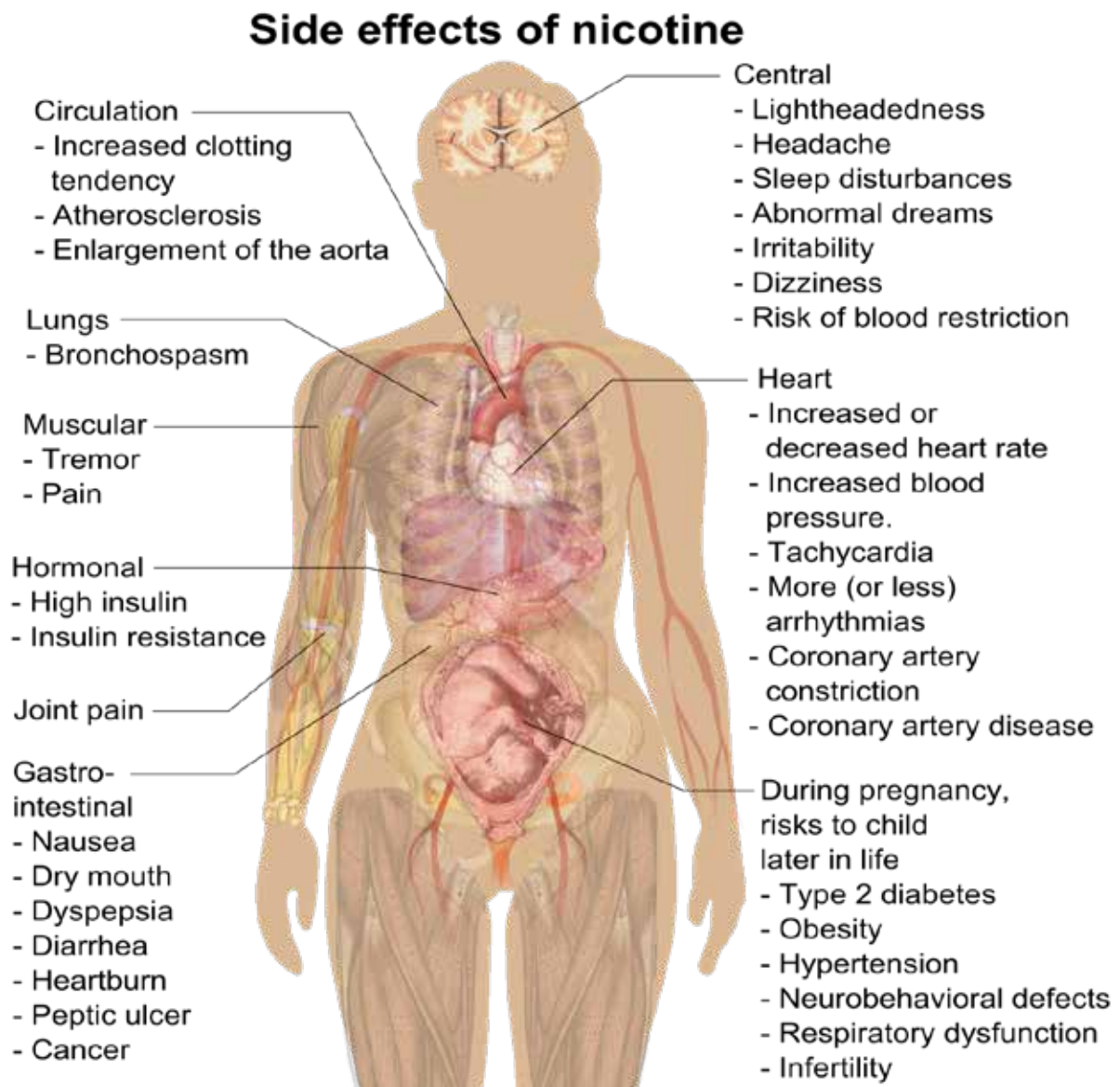
Youth who use e-cigarettes are at risk for nicotine-induced neural and behavioural alterations including:

- A strong desire or sense of compulsion to take the substance;
- A persistent desire or unsuccessful effort to reduce or control substance use;
- A physiological withdrawal state when use is reduced or ceased;
- Use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- Tolerance to the effects of the substance;
- Preoccupation with the substance use; and
- Persistent substance use despite clear evidence of harmful consequences.<sup>54</sup>

93. The side effects of nicotine are neatly captured in figure 1.6 on the next page.

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<sup>54</sup> US Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General Executive Summary. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016

**Figure 1.6 Side effects of nicotine**

Source: <https://medium.com/@freedomPods/5-reasons-to-quit-juul-671395c1b722>

### ***Risk of exposure to chemicals***

94. As noted in the introduction, although not specifically 'on point' for this RIS, concerned with the appropriate regulatory approach to nicotine containing e-cigarettes, it would not be complete without at least some reference to the risk of exposure to chemicals additional to nicotine. There is an unresolvable issue as to whether 'but for' the nicotine, noted for its

highly addictive quality, a user would not be incentivised to use e-cigarettes risking exposure to the other chemicals.

95. The October 2019 report of the National Industrial Chemicals Notification and Assessment Scheme<sup>55</sup> (from July 2020 named the Australian Industrial Chemicals Introduction Scheme (AICIS)) reported 243 chemicals *additional* to nicotine identified from published scientific literature as ingredients used in e-cigarettes; 235 of these were flavouring chemicals. Of particular concern are diketone flavourings, which have been linked to irreversible lung damage known as bronchiolitis obliterans or 'popcorn lung'.
96. On 3 December 2020, the Lung Foundation of Australia and Minderoo Foundation published the results of Curtin University tests of e-liquids used in 52 flavoured e-liquids for sale over the counter in Australia. 100% of those tested contained chemicals with unknown side effects on respiratory health and 62% contained chemicals likely to be toxic if vaped repeatedly. Some of the chemicals work to encourage addiction.<sup>56</sup>
97. E-cigarettes also emit contaminants such as metals, volatile organic compounds, phthalates, pesticides and tobacco specific nitrosamines.<sup>57</sup> Potential adverse health effects may be seen when there is sufficient concentration and exposure.<sup>58</sup>

### ***Risk of nicotine poisoning***

98. Nicotine is also highly toxic and poses significant health risks including adverse cardiovascular, respiratory and reproductive effects and negative effects on foetal and adolescent development. Ingestion of just 1-2 mL of nicotine in e-cigarette fluid refills, many of which have fruit or candy flavours and thus are attractive to children, can kill a toddler. In 2018, a young child in Victoria died from poisoning after consuming an e-liquid containing nicotine.<sup>59</sup> There is increasing international evidence of increased toxicological

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<sup>55</sup> "Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns". Available from <https://www.nicnas.gov.au/chemical-information/Topics-of-interest2/subjects/non-nicotine-e-cigarette-liquids-in-australia/summary-and-key-findings>.

<sup>56</sup> <https://lungfoundation.com.au/news/ground-breaking-australian-study-confirms-major-concerns-over-e-cigarette-safety/>

<sup>57</sup> National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems. (2018) Public Health Consequences of E-Cigarettes. Washington (DC): National Academies Press (US). [Online]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507163/>.

<sup>58</sup> NICNAS, Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns.

<sup>59</sup> See: [https://www.coronerscourt.vic.gov.au/sites/default/files/2019-07/Baby%20J\\_277318.pdf](https://www.coronerscourt.vic.gov.au/sites/default/files/2019-07/Baby%20J_277318.pdf)



consultations at poisons centres.<sup>60</sup> Between 2012 and 2017 there were 8,269 liquid nicotine exposures reported in children in the United States.<sup>61</sup>

99. The numbers of calls to Australian Poisons Information Centres about e-cigarette exposures increased considerably in the period from 2009-2016, although the overall Poisons Information Call call volume was stable at about 164 000 cases per year. Of 202 sequential e-cigarette-related cases, 38% were from relatives of children worried about their exposure to the liquid component of an e-cigarette after children were found with uncapped vials, sucking the mouthpiece, drinking from separated liquid containers, inhaling the liquid, eating the cartridge, or having splashed liquid in their eyes. Adults and adolescents were the subjects of calls in 126 cases (62%), including calls about the potential side effects of routine use or accidental ingestion, or about skin or eye splash exposures. Twelve calls followed deliberate administration for self-harm, ten by oral ingestion and two by injection.<sup>62</sup>

### **Transition from e-cigarettes to combustible tobacco use – gateway effect**

100. Research led by the ANU, reviewing worldwide evidence on e-cigarettes and smoking behaviour, found clear evidence that non-smokers who use e-cigarettes are around three times as likely to take up conventional smoking as their peers who do not use e-cigarettes. The review concluded that that gateway effect was particularly relevant to young people. All of the studies surveyed found evidence of an increased risk, with wide variation in the magnitude of this risk.<sup>63</sup>
101. The HRB has also recently reported teenagers as between three and five times more likely to start smoking if they have used e-cigarettes previously.<sup>64</sup>

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<sup>60</sup> Obertova N.; Navratil T.; Zak I.; Zakharov S. Acute exposures to e-cigarettes and heat-not-burn products reported to the Czech Toxicological Information Centre over a 7-year period (2012-2018); Vatansever M.; Glaser N.; Engel A.; Sturer A.; Klumb W.; Schaper A.; Eyer F.; Rohdenburg S.; Deters M.; Tutdibi E.; Begemann K.; Kreutz R.; Acquarone D, Study on e-liquid: Risk of poisoning and effectiveness of legal regulation, Naunyn-Schmiedeberg's Archives of Pharmacology. Conference: 86th Annual Meeting of the German Society for Experimental and Clinical Pharmacology and Toxicology, DGPT with contribution of the Arbeitsgemeinschaft für Angewandte Humanpharmakologie e. V., AGAH. Germany. 393 (Supplement 1) (pp S50), 2020

Wang B.; Liu S.; Persoskie A Poisoning exposure cases involving e-cigarettes and e-liquid in the United States, 2010-2018, *Clinical Toxicology*. 58 (6) (pp 488-494), 2020.

<sup>61</sup> Govindarajan P, Spiller HA, Casavant MJ, Chounthirath T, Smith GA. E-Cigarette and Liquid Nicotine Exposures Among Young Children. *Pediatrics* 2018;144(5).

<sup>62</sup> Wylie, Heffernan, Brown, Cairns, Lynch, Robinson. Exposures to e- cigarettes and their refills: calls to Australian Poisons Information Centres, 2009–2016; *Medical Journal of Australia*. 210 (3) (pp 126), 2019. Date of Publication: February 2019

<sup>63</sup> Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health, September 2020. Available at <http://hdl.handle.net/1885/211618>

<sup>64</sup> O'Brien D, Long J, Lee C, McCarthy A and Quigley J. Electronic cigarette use and tobacco cigarette smoking initiation in adolescents: An evidence review. Dublin: Health Research Board May 2020.

Available from:

[https://www.drugsandalcohol.ie/33170/1/Electronic\\_cigarette\\_use\\_and\\_smoking\\_initiation\\_in\\_adolescents.pdf](https://www.drugsandalcohol.ie/33170/1/Electronic_cigarette_use_and_smoking_initiation_in_adolescents.pdf).

102. In a preliminary opinion dated 23 September 2020, the Scientific Committee on Health, Environmental and Emerging Risks on electronic cigarettes also concluded that overall there is strong evidence that e-cigarettes are a gateway to smoking for young people.<sup>65</sup>
103. A 2019 analysis of 17 studies showed that use of e-cigarettes in the past 30 days among never smokers was associated with a 5.6 fold increased odds of subsequent smoking, although risk taking behaviour as well as the use of e-cigarettes specifically may be a contributing factor.<sup>66</sup>
104. Further, a 2017 systematic review<sup>67</sup> demonstrated clear cross-sectional and longitudinal evidence for an association between e-cigarette use and subsequent uptake of tobacco smoking.<sup>68</sup>
105. These findings are particularly relevant for adolescents and young adults, and the increase in e-cigarette use in adolescents in recent years raises concern that this will be followed by an increase in smoking in a few years' time.

### **Efficacy of e-cigarettes as a smoking cessation tool**

106. The 2016 ITC Four Country Smoking and Vaping Survey (conducted in the United States, England, Canada and Australia) reported that for current smokers the top three reasons for current regular nicotine containing e-cigarette use were that it was helpful for cutting down smoking (85.6%), less harmful to others (77.9%) and helpful for quitting smoking (77.4%). The top three reasons for discontinuing use of e-cigarettes were not being satisfying (77.9%), unhelpfulness for cravings (63.2%) and unhelpfulness for quitting smoking (52.4%). For ex-smokers, the top three reasons for current vaping were enjoyment (90.6%), less harmful to others (90%) and affordability (89.5%); and for discontinuing, were not needed to stay quit (77.3%), not being satisfying (49.5%) and safety concerns (44%).<sup>69</sup>
107. The evidence, however, of the efficacy of e-cigarettes as a smoking cessation tool is mixed.
108. The study from the ANU referred to at paragraph [74] found that there was insufficient evidence to conclude that e-cigarettes are effective for quitting smoking compared to other approaches, but that there are promising signs that they have potential to help. More reliable large-scale evidence is needed.<sup>70</sup>

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<sup>65</sup> [https://ec.europa.eu/health/sites/health/files/scientific\\_committees/scheer/docs/scheer\\_o\\_017.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_017.pdf)

<sup>66</sup> Khouja JN et al *Tob Control* doi:10.1136/tobaccocontrol-2019-055433

<http://dx.doi.org/10.1136/tobaccocontrol-2019-055433>

<sup>67</sup> Soneji S *et al.* Association between initial use of e-cigarettes and subsequent cigarette smoking among adolescents and young adults *JAMA Pediatr* 2017; **171**:788 doi:10.1001/jamapediatrics.2017.1488)

<sup>68</sup> McNeill, Brose, Calder et al. "[Evidence review of e-cigarettes and heated tobacco products 2018](#)" Public Health England, 2018

<sup>69</sup> Yong H H, Borland K, Cummings M, Gravely S, Thrasher J, McNeill A, Hitchmann S, Greenhalgh E, Thompson M E, Fong G T Reasons for regular vaping and for its discontinuation among smokers and recent ex-smokers: findings from the 2016 ITC Four Country Smoking and Vaping Survey, <https://onlinelibrary.wiley.com/doi/10.1111/add.14593>

<sup>70</sup> Banks E, Beckwith K, Joshy G. Summary report on use of e-cigarettes and impact on tobacco smoking uptake and cessation, relevant to the Australian context. Commissioned Report for the Australian Government Department of Health, September 2020. Available at <http://hdl.handle.net/1885/211618>

109. Also referred to at paragraph [74], the Health Research Board of Ireland published similar findings on 12 October 2020, noting that e-cigarettes are no more effective than approved and regulated NRT while their safety beyond 12 months remains unknown.<sup>71</sup>
110. There are, however, also much more positive findings that e-cigarettes are an effective smoking cessation tool. There is moderate evidence from observational studies that more frequent use of e-cigarettes is associated with an increased likelihood of cessation.<sup>7273</sup>
111. An updated Cochrane Review published in October 2020 concluded that there is ‘moderate-certainty evidence’ that e-cigarettes with nicotine increase quit rates compared to e-cigarettes without nicotine and compared to NRT. The study’s results indicate that for every 100 people using nicotine e-cigarettes to stop smoking, 10 might successfully stop, compared with only six of 100 people using NRT or nicotine-free e-cigarettes, or four of 100 people having no support or behavioural support only. However, the authors also noted that their findings were based on a small number of studies, and in some, the measured data varied widely. Notably, only four studies were considered at low risk of bias in the review and these four studies formed the basis for the report’s main comparisons; that is some studies were unpublished and some were not refereed.
112. To some extent the differences in the ANU and Cochrane conclusions on the efficacy of e-cigarettes as a smoking cessation tool arises because of the paucity of available evidence which each analysed. It is also a function of different statistical methods used. Of the 50 studies identified in the Cochrane review only four were rated as being at low risk of bias overall.
113. Notably, however, the ANU study and the Cochrane study included in their analysis a recent randomised control trial (RCT) showing a stronger impact of e-cigarettes in facilitating smoking cessation.<sup>74</sup> RCTs provide the strongest study design to protect against threats to internal validity.<sup>75</sup> On the one hand, unlike well-designed observational studies that are based on large nationally representative samples of individuals, RCTs do not reflect the ‘real world’ conditions of e-cigarette use that occurs outside of clinically ideal trial settings. Related to this, the selection criteria used to inform RCTs may limit the generalisability of

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<sup>71</sup> Quigley J, Kennelly H, L C, O’Brien D, Williams M, McCarthy A and Long J Electronic cigarettes and smoking cessation: An evidence review, available at <https://www.hrb.ie/publications/publication/electronic-cigarette-and-smoking-cessation-an-evidence-review/returnPage/1/>

<sup>72</sup> Ibid.

<sup>73</sup> National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems. (2018) Public Health Consequences of E-Cigarettes. Washington (DC): National Academies Press (US). [Online]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507163/>.

<sup>74</sup> Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N et al A randomized trial of e-cigarettes versus nicotine-replacement therapy. *New Engl J Med.* 2019;380(7):629–37. doi:10.1056/nejmoa1808779

<sup>75</sup> Internal validity is a measure of how likely the finding of an association or causal relationship is accurate, which is determined by the degree to which a study minimizes systematic error (bias). External validity addresses the extent to which a finding can be generalised to another context or to the general population.

findings to the general population.<sup>767778</sup> On the other hand, there is arguably a reasonable degree of similarity between the circumstances of an RCT and the circumstances in which a person is supported by a medical professional to stop smoking.

### **Risk of smoking resumption in e-cigarette users and dual users**

114. Reducing uses of e-cigarettes whilst continuing to smoke combustible cigarettes may not reduce the health risks. For example, a recent meta-analysis of prospective cohort studies examining cardiovascular disease risk in light and moderate smokers found that smoking a single cigarette per day still carried half the risk of a cardiovascular event as smoking 20 cigarettes per day.<sup>79</sup>
115. The recent ANU study referred to at paragraph [74] found that of the limited available evidence there was an indication that former smokers who use e-cigarettes are more than twice as likely to relapse and resume smoking compared to former smokers who have not used e-cigarettes.

### **Consumer problem - Conclusion**

116. Nicotine containing e-cigarettes present risks to users, act as a gateway to smoking for ever users particularly for adolescents and young adults and, although less harmful than smoking, the evidence on their role as a smoking cessation tool is equivocal. There have also been a number of accidental poisonings of children. The precautionary principle (encouraging action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation) demands a regulatory response. That response is a function of the cause of the problem, present Commonwealth regulation.

### **The problem with present Commonwealth regulation**

117. It is widely accepted that the rapid increase in use of nicotine containing e-cigarettes including by adolescents and young adults is attributable to the ease with which the products may be purchased online from international retailers.<sup>80</sup> As set out in the

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<sup>76</sup> National Academies of Science, Engineering, and Medicine 2018. Public Health Consequences of E-cigarettes. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK507176/>

<sup>77</sup> Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) Report by WHO. 2016. Available at: [https://www.who.int/fctc/cop/cop7/FCTC\\_COP\\_7\\_11\\_EN.pdf](https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf)

<sup>78</sup> Also see: <https://simonchapman6.com/2020/10/15/would-you-take-a-drug-that-failed-with-90-of-users-new-cochrane-data-on-vaping-success/>

<sup>79</sup> Hackshaw, Morris, Boniface, et al. "Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports" (2018) 360 BMJ, j5855. And Shahab L, Goniewicz ML, Blount BC, et al. Nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users: a cross-sectional study. *Ann Intern Med.* 2017;166(6):390-400 reported in Reported in Green M J, Lisay Grau, Sweeting H and Benzeval M Socioeconomic patterning of vaping by smoking status among UK adults and youth at <https://bmcpublikealth.biomedcentral.com/articles/10.1186/s12889-020-8270-3>.

<sup>80</sup> Braak, DC, Cummings, KM, Naahas G, Heckman B W, Borland R, Fong G T, Hammon D, Boudreau C, McNeill A, Levey DT and Shand C Where Do Vapers Buy Their Vaping Supplies? Findings from the International Tobacco Control 4 Country Smoking and Vaping Survey <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6388194/>

Introduction, this arises because of the current lacuna in regulation of nicotine containing e-cigarettes (and e-cigarette liquids) at the Commonwealth level relative to state and territory regulation. There is no effective Commonwealth restriction on the importation of nicotine containing e-cigarettes and relevant refills ordered from overseas suppliers.

118. It follows that there are no effective powers at present for the Australian Border Force to intercept these products at the border. It is also almost impossible for state and territory government agencies to police such purchase or use.

119. The outcome of this lacuna is:

- an unchecked opportunity for increased use of nicotine containing e-cigarettes by ever users particularly adolescents and young adults – which has indeed materialised in increased use;
- purposeful (or otherwise) ignorance of what support is available for effective smoking cessation particularly from a medical practitioner. A patient’s medical practitioner is arguably uniquely placed to give the support required to make appropriately risk based health choices. A patient’s doctor would work in partnership with his or her patient to take account of the patient’s physical and mental health as well as use of medication to advise on the most appropriate measure to aid smoking cessation – whether it be a prescription medicine, NRT or behavioural management; and
- failure to protect children from accidental poisoning by consumption of nicotine e-liquid refills.

## Need for regulatory action

120. The Australian Government Department of Health's strategic priority is to protect the health and safety of the Australian community. As a part of the Department, the TGA's role in delivering on this commitment is through effective, timely and risk proportionate regulation of therapeutic goods and poisons (in accordance with the requirements of the TG Act).
121. It is in the interests of the Australian public that the Commonwealth deliver on its commitment to the precautionary approach. State and territory government commitment to that principle is frustrated because of the failure of Commonwealth regulation.
122. The Department therefore considers that some form of action is needed because of the effect of the lacuna in Commonwealth regulation of importation of nicotine containing e-cigarettes (and e-cigarette liquids) relative to state and territory prohibition on their supply.
123. There is also an interest in clarity and consistency of regulation by the Commonwealth and states and territories; that is in uniformity of regulation of the supply of nicotine containing e-cigarettes *into* Australia and *within* each jurisdiction in Australia as well as their possession and use.

## The objective of the intervention

124. The objective of the intervention is to protect the health of the Australian community by:
  - a. arresting the recent rapid increase in use of nicotine containing e-cigarettes by ever users particularly adolescents and young adults (avoid the 'on ramp' for non-smokers especially youth);
  - b. providing to patients who want to stop smoking efficacious support, not already available (such as the Quit program) - likely in the form of medical practitioner support, including considering whether to prescribe nicotine containing e-cigarettes (providing for the 'off ramp' for smokers)
    - i. It is well established in the smoking cessation treatment literature that combining pharmacotherapy with behavioural counselling increases the odds of smoking cessation over pharmacotherapy or counselling alone;<sup>81</sup>. The US Surgeon General notes the 2015 'Grade A' recommendation that medical practitioners deliver brief tobacco cessation intervention: 'Even brief (less than 3 minutes) advice from a physician improves cessation

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<sup>81</sup> Clinical Guidelines for Prescribing Pharmacotherapy for Smoking Cessation. Content Last Reviewed December 2012. Agency for Healthcare Research and Quality; Rockville, MD, USA: Available online: <https://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/prescrib.html>

rates'<sup>82</sup> and is highly cost effective.<sup>83</sup> The 5As method is the gold standard for delivering this intervention, effective in increasing tobacco cessation and quit attempts among patients as well as increasing engagement in other empirically validated cessation treatments;<sup>84</sup> and

- c. reducing the likelihood of child poisoning by accidental consumption of nicotine e-liquids.

## The regulatory tools available to intervene

125. The regulatory tools available to the Department are:

1. A public awareness campaign designed to address the objectives of intervention.
2. Inclusion of nicotine for all human use in the Poisons Standard as a prescription only medicine with a requirement for a child resistant closure for the container. This removes its availability to ever users particularly adolescents and young adults as an opportunity to initiate use of nicotine, whilst maintaining its availability for smokers seeking the assistance of nicotine containing e-cigarettes as an aid to stop smoking. It avoids accidental poisonings of children by consumption of nicotine.
3. Jointly, the public awareness campaign and the amended entry of nicotine in the Poisons Standard and the child resistant closure requirement.

126. Whether each of the options would deliver on the regulatory objectives is assessed further below.

127. Consideration has been given to whether there might be a regulatory option falling between Option 2 and Option 3, that is to say a 'lighter touch' option than Option 3 that would address the regulatory objectives.

128. However, in Australia, with the present equivocal state of evidence of efficacy and evidence of the risks of use of e-cigarettes to individual health and to public health more generally, the commitment to the precautionary principle and the regulatory objectives, particularly the support of a medical practitioner to assist a patient to stop smoking, another option is not presently viable. In this regard, it is notable that Option 3 includes a requirement for a child resistant closure for nicotine e-liquids.

129. Some of the submissions to the Delegate's invitation advocated that nicotine containing e-cigarettes be available as Pharmacist Only Medicines (Schedule 3). This is not consistent

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<sup>82</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>83</sup> M V Maciosek, A LaFrance, S D Dehmer, D A McGree, T J Flottemesh, Z Xu, L Solberg, Updated priorities among effective clinical preventive services *Ann Fam Med* 2017 Jan; 15(1):14-22. doi: 10.1370/afm.2017. Available from: <https://pubmed.ncbi.nlm.nih.gov/28376457/>

<sup>84</sup> Ibid

with the regulatory objective for support for a smoker to quit (see paragraph [14]). Further, the need to control the access and duration of a therapy by a doctor is consistent with the Schedule 4 Scheduling Factors, according to the [Scheduling Policy Framework \(SPF\)](#). Taking account of the factors mentioned in the previous paragraph, it is in the interest of promoting public health outcomes to change the current access controls on nicotine e-cigarettes to ensure that they are only accessible under the supervision of a doctor. However, this does not preclude a down scheduling application in the future if there is sufficient supporting evidence, for example, based on safety data from an Australian approved product should one be included on the ARTG. Patches and gums were initially approved as prescription medicines and were down-scheduled when supporting safety data became available.

130. Further, a suggestion that mandating product quality might be one such 'lighter touch' regulatory option belies the associated complexity. As a stand-alone measure, it fails completely to meet any of the three regulatory objectives. In a sense, it is an extension of the preference for e-cigarettes to be treated as consumer goods, which is the primary submission of the Australia Lottery and Newsagents Association and the National Retail Association. The underlying concern is with product safety, not with regulation of their access, which is the focus of the Department's considerations.
131. Nevertheless, it is notable that there was, amongst those making submissions to the Delegate's invitation made on publication of the interim decision, whether opposing or supporting the Delegate's interim decision, support for standards where there are no nicotine containing e-cigarettes entered on the ARTG. The Delegate has therefore indicated that there would be benefit from further work with stakeholders to develop appropriate standards that would apply to unapproved products. These may include labelling requirements, warnings, limits on concentration and volumes and excipients.
132. In this regard, it is relevant to consider what 'product quality' obligations are presently imposed in countries from which Australian users largely import nicotine containing e-cigarettes. Product quality is prescribed by two of the three nations from which the majority of imports of nicotine containing e-cigarettes is presently made, the US and the United Kingdom (see the Tobacco and Related Products Regulations 2016 (UK) and see the European Tobacco Products Directive 2014/14/EU (TPD which came into effect in 2016)). The *Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020* (New Zealand) anticipates regulations would be made on the ingredients of 'vaping products' and the packaging and labelling thereof. Finally, product quality is also necessarily part of the TGA's evaluation of a medicine for which an application for registration has been made. The suggestion is that there is high likelihood that, particularly noting the demand from both users and anticipated prescribers for it, the market will deliver the assurance of product quality. Any Australian prescribed product standard would have little, if any, work to do. Nevertheless, it remains appropriate to work to prepare relevant standards, in this way meeting the Delegate's reflection (see the previous paragraph).



## Consultation

133. The Delegate's proposal to include nicotine for all human use in Schedule 4 of the Poisons Standard (a prescription only medicine) was published on 17 April 2020.<sup>85</sup> The Delegate received 13 submissions in response to the invitation for submissions, which closed on 18 May 2020 as well as advice from the Advisory Committee on Medicines and Chemicals Scheduling in joint session. The Committee recommended moving nicotine for human use to Schedule 4 while retaining the current exemptions for tobacco and certain smoking cessation products. [The Committee also recommended deleting the Schedule 6 entry and creating an Appendix D listing for nicotine in the current Poisons Standard.]<sup>86</sup>
134. The interim decision of the Delegate was published on 23 September 2020 with an invitation for public submissions to be received on or before 12 November 2020. The Delegate included a specific invitation for comments on child resistant closures for liquid nicotine products.
135. On 8 and 9 October 2020, the TGA hosted three webinars on the implications of the decision if it were made final, two were specifically for consumers and health care practitioners and one was for the medical supply industry. In total, 215 external stakeholders attended the webinars. Considerable time at each webinar was dedicated to answering questions.
136. On 22 October 2020, the TGA published the information webinars<sup>87</sup> along with a list of answers to 31 frequently asked questions (grouped from the 180 received before and during the webinars).<sup>88</sup> The questions and answers addressed issues associated with the arrangements for supply and with prescribing e-cigarettes along with the evidence for the use of nicotine and other regulatory approaches, the impact of the cost and the next steps.
137. A total of 2,385 submissions was received, in response to the Delegate's invitation. In considering the final scheduling decision, the Delegate has expressly had regard to the following salient points raised by those submissions. The Delegate's reason for decision incorporates and responds to these considerations. They are also relevantly dealt with in this RIS under the analysis of impact of Option 3.
138. The vast majority of those submissions, that is 2,243, are largely singular in their message - relating compelling personal stories of using nicotine containing e-cigarettes to quit smoking successfully. Many of these submitters referenced the claim that nicotine containing e-cigarettes are 95% less harmful than combustible cigarettes. They also noted the personal inconvenience of having to make, and attend, an appointment for a consultation with a doctor for those who presently use nicotine containing e-cigarettes. Paragraphs [87] to [90] explain the import of the 95% claim and the discussion on Option 3 further records responses to users' testimonials.
139. A number of stakeholders, including the RANZCP, highlighted the importance of considering the impacts of the scheduling decision on vulnerable populations, such people with mental

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<sup>85</sup> <https://www.tga.gov.au/sites/default/files/consultation-proposed-amendments-poisons-standard-acms-and-joint-acmsaccs-meetings-june-2020.pdf>

<sup>86</sup>

<sup>87</sup> <https://www.tga.gov.au/information-webinar-proposed-changes-way-nicotine-supplied>

<sup>88</sup> <https://www.tga.gov.au/nicotine-webinars-frequently-asked-questions-faq>

illness who use or may benefit from using nicotine e-cigarettes. Consumers also voiced concerns regarding criminalising the possession of nicotine containing e-cigarettes.

140. A number of submissions also drew comparisons with NRT such as patches and gums that are available for retail sale. NRT products approved in Australia deliver nicotine to the body through the lining of the mouth and cheeks (sprays, inhalator, gums and lozenges) or the skin (patches) and are designed to reduce nicotine withdrawal and cravings while minimising the potential for abuse.
141. Health peak bodies, professional organisations and researchers, including the Cancer Council of Australia, the Royal Australian College of General Practitioners, the Public Health Association of Australia, the Pharmacy Guild of Australia and the Australian Medical Association expressed support for the interim decision. Support was largely couched by reference to support for medical practitioners working with their patients in the manner advised by the Royal Australian College of General Practitioners [Supporting smoking cessation - A guide for health professionals \(second edition, December 2019\)](#) (RACGP guidelines). Some voiced the concern that use of nicotine through prescription will create a misconception, contrary to the evidence, that it confers a therapeutic benefit. A call for information and support to prescribers and consumers was seen as ameliorating this risk.
142. Many organisations, while supportive of the interim decision, also highlighted challenges for implementation in the absence of an approved product included on the ARTG. These submissions also called for sufficient time to develop robust prescribing guidelines and the development of quality and safety standards for unapproved products, which would address excipients, labelling, limits on nicotine concentrations and volumes as well as requirements for child resistant closures.
143. As noted at paragraph [131], the call for quality and safety standards for nicotine e-cigarettes received support from both supporters and opponents of the decision. Stakeholders have highlighted the importance of standards in the current circumstances, where there are no nicotine containing e-cigarettes entered on the ARTG, and consumers will be accessing unapproved products.
144. Submissions from vaping businesses and retailers including the Australia Lottery and Newsagents Association and the National Retail Association opposed the interim decision advocating for nicotine containing e-cigarettes to be regulated as consumer products. However, these submissions are not consistent with the policy objectives articulated at paragraph [14]. Additionally, as earlier noted and the Delegate records in the final decision, nicotine containing e-cigarettes meet the Schedule 4 factors in the Scheduling Policy Framework. In addition, nicotine in e-cigarettes or other novel delivery systems does not meet the principles of 'reasonable safety' described in the Scheduling Handbook, which guides the assessment of whether a substance is suitable for exemption from scheduling.
145. There was overwhelming support in the submissions for measures that would require child resistant closures for liquid nicotine products. Many individual users of nicotine e-cigarettes noted in their submissions that the products they are importing are already supplied with child resistant closures.
146. The Senate Select Committee on Tobacco Harm Reduction established on 6 October 2020 inquired into tobacco reduction strategies, received submissions until 5 November and is due to report on 18 December 2020. At the time of writing, a total of 900 submissions was

published as having been received. The Committee received 8,303 form letters. The Department, along with other invitees, appeared before the Committee's hearings in Canberra on 13 November 2020. Another day of public hearings was held in Sydney on 19 November 2020.<sup>89</sup> Where relevant, to Option 3 in particular, the RIS documents some of those submissions and how they have been factored into considerations.

147. Article 5.3 of the WHO Framework Convention on Tobacco Control requires that 'in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and vested interests of the tobacco industry in accordance with national law.' The Guidelines also require Parties 'establish measures to limit interactions with the tobacco industry and ensure the transparency of those interactions that occur.' Acting consistently with this international obligation, the Department has therefore consciously not engaged with the tobacco industry in this public health policy issue on tobacco.
148. The Department of Health also engaged with medical practitioner experts including the Presidents of the Australian Medical Association and the RACGP along with members of the RACGP established Expert Advisory Group, which contributed to the second edition of the RACGP's supporting smoking cessation guideline. This included Professor Nicholas Zwar, Executive Dean, Faculty of Health Sciences and Medicine, Bond University, Queensland, Associated Professor Matthew Coleman, Rural and Remote Mental Health Practice, Rural Clinical School of Western Australia, University of Western Australia in conversation with Dr Shalini Arunogiri, Chair Faculty of Addiction Psychiatry, RANZCP, RACGP in-house practitioner experts on smoking cessation, the National Drug and Alcohol Research Centre and Professor Emily Banks, ANU Research School of Population Health.
149. The Department also participated in a teleconference with the CEO of the National Retail Association, Ms Dominique Lamb.

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<sup>89</sup><https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22committees%2Fcommmsen%2Fa7445df9-6fbe-4609-97d3-ce406a75366f%2F0001%22>

## Policy options considered

150. The problem, its root cause and the objective of the regulatory response suggest that there are four potential options. Table 1, replicated below, contains the key options explored in the RIS to fill the regulatory lacuna.

Option	Elements
<b>Option 1</b>	Maintain the status quo (no change).
<b>Option 2</b>	Public awareness campaign - stop initiation / dependence on e-cigarette / smoking cessation.
<b>Option 3</b>	Nicotine for all human use is included in the Poisons Standard as a prescription only medicine with a requirement for a child resistant closure for the container.
<b>Option 4</b>	Combination of options 2 and 3.

## Criteria for assessing options

151. Some of the criteria used in assessing various options are:

- The degree by which the option would likely address the identified problem;
- The benefits to be attained;
- The overall regulatory burden;
- Impacts on Australian businesses; and
- Impacts on availability of e-cigarettes as an aid to stop smoking.

152. The criteria are not stand-alone and have been considered together in determining the option offering the highest overall net benefit. Higher emphasis has been placed on the degree by which the option would likely address the identified actual cause of the problem and the identified public health considerations associated with the availability of nicotine containing e-cigarettes and the continued use of combustible cigarettes.

153. Furthermore, the criteria are assessed with respect to those most-affected. This detailed analysis for each of the Options is set out in tables 6, 7 and 8 in Annexure A. The relevant demographics are:

- those vulnerable to the health risks of e-cigarettes. These include:
  - i. **youth**, (representing ever users) who may be induced to start smoking and / or develop nicotine dependence (or be otherwise harmed) by e-cigarettes,
  - ii. **children**, who may be poisoned by accidental consumption of nicotine e-liquid,
- those who seek to use e-cigarettes to aid smoking cessation including:

- i. **ex-smokers**, who are susceptible to relapse / resumption of smoking
- ii. **current smokers**, who are seeking to quit smoking
- those involved in the manufacture, distribution, and regulation of e-cigarettes. These include:
  - i. **retailers**, who are interested in maintaining their revenue;
  - ii. **wholesalers**, who are interested in maintaining supply to domestic retailers;
  - iii. **medical practitioners**, who have a role in supporting patients to stop smoking which may include prescription of e-cigarette for this purpose;
  - iv. **pharmacists**, who have a role in supplying e-cigarettes (for smoking cessation); and
- **the Department**, which initiates and implements policy designed to achieve the regulatory objectives.

154. In this regard, it is important to bear in mind that, as earlier noted, in making any scheduling decision, the Delegate is exclusively bound by the criteria specified by the TG Act and the TG Regulations. Accordingly, consistent with *Eve Hemp Pty Limited v Secretary to the Department of Health* [2017] FCA 1051, the Delegate will inform the scheduling decision having regard to those matters the RIS addresses which are set out in s 52E(1) of the TG Act.<sup>90</sup> The Delegate *may* have regard to other matters canvassed which fall within the subject matter, scope and purpose of Part 6-3 of the TG Act construed in context (emphasis added), that is matters concerned with health and safety.

## Option 1. Maintaining the status quo

155. Under the status quo, e-cigarettes containing nicotine would continue to be able to be imported under the personal importation scheme and otherwise under the TG Act without the necessity for the support of a prescription. Nicotine containing e-cigarettes would remain easily accessible by ever users particularly adolescents and young adults, either by way of personal importation, or by way of commercial importation for unlawful domestic sale. There would be no requirement for medical support in the quest for a smoker to stop smoking. There would be no measures to address the risk of child poisoning.

156. Accordingly, the status quo would therefore not address the policy objectives to

- arrest the recent rapid increase in use of nicotine containing e-cigarettes by ever users particularly adolescents and young adults;
- provide to patients who want to stop smoking efficacious support, not already available (such as the Quit program) likely in the form of medical practitioner

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<sup>90</sup> See further paragraph [324] of Annexure B.

support, including considering whether to prescribe nicotine containing e-cigarettes; and

- reduce the likelihood of child poisoning by accidental consumption of nicotine.

157. A detailed assessment by cohort of the impact of maintaining the status quo is set out in Table 6 under Option 1, maintaining the status quo in Annexure A. That analysis is captured at a high level immediately below, followed by a summary assessment.

### **Analysis of impact of Option 1: Maintaining the status quo**

158. The disadvantages to users of nicotine containing e-cigarettes overwhelm the 'benefit' of absence of regulatory impost.

159. First ever users, represented primarily by a 'youth' catchall to describe adolescents and young adults. Whilst nicotine containing e-cigarettes remain available to youth none of the public health risks associated with their use by this cohort is addressed – particularly noting the vulnerability of the adolescent brain to the rewarding effects of nicotine thereby risking the introduction of a whole new generation of nicotine addicts with the high risk of taking up smoking. Among other things, this motivated the US Surgeon General to declare that youth use of any tobacco products including e-cigarettes is unsafe.

160. For smokers, the absence of an additional incentive to use NRT or to seek a medical practitioner's assistance to stop smoking with the risk of less success in ceasing to smoke persists. There is the risk of dual use, long-term use of e-cigarettes as a substitute for combustible cigarettes, exposure to chemicals and possible injury from malfunctioning and possible exposure to commission of a criminal offence or civil penalty contravention. The bald statistic that 21,000 Australians die from smoking related illnesses each year emphasises the potential impact on costs to individual health and to the public health system from the failure to act. Table 6 sets out detailed evaluations of tangible health care costs.

161. The risk of accidental nicotine poisoning by children, our most vulnerable population, also persists with risk of paying the ultimate price - death.

162. The status quo is a complete failure to heed the evidence that e-cigarettes are a gateway to smoking and the evidence of risks to health. It eschews the precautionary principle.

163. Medical practitioners and pharmacists are not given the critical role, which they may play in supporting patients' health / public health outcomes – for smokers in stopping smoking and for the public purse in reduced adverse public health outcomes. (as to which see the comments under youth and smokers and former smokers).

164. Because it is unlawful in every state and territory to sell nicotine containing e-cigarettes there is no impact of the status quo on those wholesalers and retailers of non-nicotine containing e-cigarettes or, separately, the devices. It is inappropriate to comment on unlawful sales of nicotine containing e-cigarettes.

### **Summary of assessment of Option 1: Maintaining the status quo**

165. The application of the criteria for assessing each regulatory option demonstrates that the status quo fails to address the problem and to deliver on the objectives of regulation. It fails

to balance the objectives of supporting smokers to stop smoking with protecting ever users particularly adolescents and young adults from risks associated with the use of nicotine containing e-cigarettes; it also perpetuates the risk of nicotine poisoning of young children. Businesses would continue to risk unlawful sales of nicotine containing e-cigarettes.

166. Neither the absence of an additional regulatory burden nor the absence of an outcome, which supports unlawful behaviour (without seeking to address the reasons leading to that behaviour), is a reasonable basis for supporting the status quo. It is not a basis to justify the failure to deliver on these objectives.
167. In short, the outcome of the application of the criteria for assessing the regulatory options is that Option 1, the status quo, is not the preferable response.

## Option 2. Public awareness campaign – smoking cessation / stop initiation of use of e-cigarettes

Figure 2.1: Flow chart depicting education campaign



168. Option 2 would see the Australian Government (working with states and territories) conducting a public awareness campaign to more clearly address the information gaps, to increase awareness:

- among ever users particularly adolescents and young adults of the health risks of nicotine addiction and the use of e-cigarettes including the risk of acting as a gateway to smoking; and
  - i. In 2018, the United States Food and Drug Administration (FDA) launched the 'Real Cost' Youth E-cigarette Prevention Campaign to engage youth with public health messages about the risks of e-cigarette use.<sup>9192</sup>
    - The campaign has used advertising on digital and social media sites, as well as posters with e-cigarette prevention messages displayed in high schools.
    - As part of the campaign, television advertisements were also launched in 2019 to educate children further about the dangers of e-cigarette use.
    - With the rates of use of nicotine, containing e-cigarettes in US high schools almost tripling over the period 2017 to 2019 it is unclear how effective this campaign has been.
- to smokers of the evidence of the negative effects of smoking and of the benefits of smoking cessation.
  - i. The National Tobacco Campaign (the NTC) is a vital component of the Australian Government's suite of tobacco control initiatives, designed to work in concert with other tobacco control and prevention measures to reduce the burden of smoking on the Australian community.
    1. Many campaigns have been run under the NTC to inform the public of the harms of tobacco use, motivate smokers to quit and recent quitters to continue smoking abstinence, discourage the uptake of smoking and reshape social norms about smoking. For these campaigns, reach, intensity, duration and messaging were varied to capture different audiences.

<sup>91</sup> See: <https://www.fda.gov/tobacco-products/public-health-education/real-cost-campaign#1>

<sup>92</sup> See: <https://www.fda.gov/news-events/press-announcements/fda-launches-its-first-youth-e-cigarette-prevention-tv-ads-plans-new-educational-resources-agency>



2. The campaign – More Targeted Approach was developed to complement the mainstream campaign and focused on Aboriginal and Torres Strait Islander people, culturally and linguistically diverse groups, people living in socio-economically-disadvantaged areas, people with mental illness, prisoners and pregnant women and their partners. Under this program, advertisements were run concurrently with the provision of additional support resources.
    - ii. The new NTC would target all smokers aged 18 to 55 years, including hard-to-reach and vulnerable audiences.
    - iii. States and territories have also implemented their own public education and media campaigns to reduce smoking prevalence.<sup>93</sup>
169. Consistent with the usual form of the NTC, the campaign would be a form of ‘moral suasion’ both to convince adolescents, young adults and smokers to change their behaviour to, in the case of the former, not take up the use of nicotine containing e-cigarettes as well as to cease use of e-cigarettes. In the case of the latter, the desired behaviour change is cessation of smoking.
170. The awareness programme for adolescents and young adults would be informed by consultations with secondary school and tertiary educators. Promotion within secondary schools, perhaps as part of the curriculum, and tertiary education settings and with the benefit of the most popular social medium for the target audience would be a minimum.<sup>94</sup> Insofar as youth addicted to e-cigarettes is concerned, the United States Surgeon General notes that there is very little data about effective interventions for youth e-cigarette cessation.<sup>95</sup>
171. For smokers, it would be proposed that the next iteration of the NTC would build on existing aspects of that campaign first initiated in 1997 notably the NTC – More Targeted Approach. The results of that campaign show that exposure to tobacco control advertising in the previous three months was associated with a greater likelihood of making a quit attempt.<sup>96</sup> Further, for a greater chance of efficacy, the campaign would recognise that the media landscape in Australia has changed dramatically in recent years with some audiences moving away from frequent and heavy television consumption towards online platforms and digital media channels. The profile of current smokers would also inform the design of

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<sup>93</sup> Further information on campaigns by jurisdiction can be found at:

<https://www.tobaccoinustralia.org.au/chapter-14-social-marketing/14-3-public-education-campaigns-to-discourage-smoking>.

<sup>94</sup> Preventing tobacco use among youth and young adults: a report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, CDC; 2012. [https://www.cdc.gov/tobacco/data\\_statistics/sgr/2012/consumer\\_booklet/pdfs/consumer.pdf](https://www.cdc.gov/tobacco/data_statistics/sgr/2012/consumer_booklet/pdfs/consumer.pdf)

<sup>95</sup> US Preventive Services Task Force. Draft Recommendation Statement: Prevention and Cessation of Tobacco Use in Children and Adolescents: Primary Care Interventions. USPSTF website. <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/tobacco-and-nicotine-use-prevention-in-children-and-adolescents-primary-care-interventions>. and Janssen BP, Walley SC, AAP Section on Tobacco Control. E-Cigarettes and Similar Devices. *Pediatrics*. 2019;143(2) e20183652

<sup>96</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

the campaign and the appropriate media for its distribution. Specifically, evidence that people from lower socio economic status groups and Aboriginal and Torres Strait Islander people, people experiencing homelessness and people with mental health issues experience much higher rates of smoking than the general population would inform the medium and the message.<sup>97</sup>

172. Consideration would be given to use of languages other than English.
173. The campaign could also build on work of other organisations such as SANE Australia, which provides information on their website for people with mental illness about smoking cessation,<sup>98,99</sup> and Tackling Indigenous Smoking.<sup>100</sup> The US *Tips from Former Smokers* campaign and the New Zealand *Quit Strong* campaign launched in August 2020 may be useful models.<sup>101</sup> The former includes graphic and negative depictions of health harms along with testimonials – consistently found to be the most effective at prompting quitting behaviours.<sup>102</sup> At a minimum, each advertisement would include a tag to the *Quit* banner.<sup>103</sup>
174. The education campaign is likely to have some success in achieving its objectives both for never young smokers and smokers. For example, during 2012-18, the *Tips from Former Smokers* campaign was associated with an estimated 16.4 million quit attempts and more than one million sustained quits among US adults.<sup>104</sup> Nevertheless, sustained quits represents only 6% of the numbers of attempts and the success of the ‘Real Cost’ campaign earlier referred to is, in view of the almost tripling of use of e-cigarettes by US high school students, at least open to interpretation.
175. Campaigns are reasonably cost effective. The US Surgeon General estimated that each year in the United States, annual health care spending attributed to smoking exceeds \$170 billion. The first year of the *Tips from Former Smokers* national campaign cost less than

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<sup>97</sup> Scollo M, Winstanley M. Tobacco in Australia: facts and issues. Melbourne: Cancer Council Victoria; 2019 [cited 2019 Nov 4]. Available from: [www.TobaccoInAustralia.org.au](http://www.TobaccoInAustralia.org.au). referred to in Beasley SJ, Barker A, Murphy M, Roderick T, Carroll T. What makes an effective antismoking campaign: insights from the trenches. *Public Health Res Pract.* 2020;30(3):e3032021. <https://doi.org/10.17061/phrp3032021>.

<sup>98</sup> Beasley SJ, Barker A, Murphy M, Roderick T, Carroll T. What makes an effective antismoking campaign: insights from the trenches. *Public Health Res Pract.* 2020;30(3):e3032021.

<https://doi.org/10.17061/phrp3032021>

<sup>99</sup> [www.sane.org/information-stories/facts-and-guides/smoking-and-mental-illness#guide](http://www.sane.org/information-stories/facts-and-guides/smoking-and-mental-illness#guide)

<sup>100</sup> <https://tacklingsmoking.org.au>

<sup>101</sup> Available at: <https://quitstrong.nz/>.

<sup>102</sup> Beasley SJ, Barker A, Murphy M, Roderick T, Carroll T. What makes an effective antismoking campaign: insights from the trenches. *Public Health Res Pract.* 2020;30(3):e3032021.

<https://doi.org/10.17061/phrp3032021>

<sup>103</sup> Ibid

<sup>104</sup> Murphy-Hoefer R, Davis KC, King BA, Beistle D, Rodes R, Graffunder C. Preventing Chronic Disease, “Association between Tips From Former Smokers Campaign and Smoking Cessation Among Adults, United States 2012-18

\$500 for every smoker who quit.<sup>105</sup> Also see the discussion of the results of the 1997 NTC at paragraph [273].

176. In addition to the usual negative messages of the effects of smoking and the benefits of quitting, the campaign could encourage smokers to discuss their smoking addiction with their medical practitioner, which would likely materially assist in the quest to stop smoking and to reduce the risk of long-term substitution use of nicotine containing e-cigarettes.
177. As users will likely be exposed to campaign material as part of their day-to-day activities, the Department's communications will form but part of the broader messaging consumed in any given day. Furthermore, it is likely that the delivery of information will be incorporated within current teaching settings and thus will not increase the contact hours for teachers nor students but rather form part of day-to-day activities. The public education awareness activities would therefore not result in any additional time imposed on (potential) users. Noetic has therefore assessed that there is no additional regulatory cost associated with this option.
178. However, it is also possible that the public awareness campaign will have no impact on the behaviour of those whose behaviour it is intended to influence. Whilst this option may assist consumers in making informed decisions and identifying risks of the use of nicotine containing e-cigarettes, the temptation of ease of import of nicotine containing e-cigarettes would remain. The temptation is likely to be especially strong for adolescents and young adults for whom the popularity of e-cigarettes is a function, not only of their addictive capacity and pharmacokinetic effect, but also of their perceived enhancement to image and opportunity for social engagement, ease of concealment and availability in a variety of flavours.
179. Hence, whilst the campaign would address the *outcome* of the regulatory lacuna between Commonwealth and state and territory law, it would not address the underlying problem. Because the lack of information on the part of users of nicotine containing e-cigarettes is not the root cause of the problem but a symptom of it, an education campaign is not likely the most appropriate response to the identified problem.
180. Further, so far as smoking cessation is concerned, the US Surgeon General reports that the 'current paradigm for smoking cessation conceptualises nicotine addiction as a chronic, relapsing disorder that benefits from long-term management and intensive treatment approaches<sup>106</sup>.' More intensive and longer behavioural and pharmacological interventions

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<sup>105</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>106</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

together is the optimal treatment based on 'overwhelming scientific evidence'.<sup>107</sup> This is also consistent with the terms of recommendation 15 of the RACGP guidelines

181. Such a campaign is therefore more likely to increase its effectiveness if it is integrated with an alternative option, which would address the underlying cause of the problem. It is also likely more efficacious if married with systematic support for smokers in a clinical practice, captured in the 5As for smoking cessation in Australian General Practice as set out in the RACGP guidelines: ask, assess, advise, assist, arrange. Accordingly, its efficacy would likely be increased if married with Option 3.
182. An Australian Government campaign is also likely to be costly to the Budget – the actual required amount a function of its design. A potential range of commitment is a minimum of \$10 million for a one off 6 week campaign and up to \$40 million for four 6 week campaigns with geo-targeting – identifying high smoking prevalence and low socio economic communities with extra localised exposure to effective (and potentially to locally created) messages with the engagement of local media, leaders and health professionals.
183. A detailed assessment by cohort of the impact of maintaining the status quo is set out under Table 7, Option 2 public awareness campaign, in Annexure A. That analysis is captured at a high level immediately below, followed by a summary assessment.

### **Summary of assessment of Option 2: Public awareness campaign**

184. The following three reasons would suggest that Option 2 is a relatively attractive regulatory option:
- evidence of the success of past smoking cessation education campaigns suggests that this option will have some success in arresting the uptake of nicotine containing e-cigarettes by youth and assisting smokers to cease smoking as well as, to some degree, addressing the risk of accidental nicotine poisoning by children;
  - the regulatory burden is nil; and
  - any impact on a market (in e-cigarettes or devices) would be indirect.
185. Such a conclusion, however, inappropriately gives weight to the value to businesses of unlawful behaviour. It also applies a narrow lens to the required assessment of each regulatory option. Application of the first criteria for assessing the regulatory options, the degree to which the option would likely address the identified problem, indicates that Option 2 falls short in delivering on the regulatory objectives. Indeed, when appropriate consideration is given to the gravity of:
- the evidence that tobacco use is associated with co-morbidities including that it remains a leading cause of preventable death and disability in Australia

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<sup>107</sup> Ibid

(estimated to have killed 21,000 Australians in 2015)<sup>108</sup> and the negative impact on individual lives and the community more generally (see earlier references to the social (including health) costs of tobacco use in Australia;

- the risk of the gateway effect on adolescents and young adults of use of e-cigarettes to smoking

there is a real risk that Option 2 falls relatively short on delivering the identified regulatory objectives. Because the lack of information on the part of users of nicotine containing e-cigarettes is not the root cause of the problem but a symptom of it, a public awareness campaign is very likely not the most effective response in delivering on the regulatory objectives; that is Option 3.

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<sup>108</sup> Australian Institute of Health and Welfare. Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no. 21. Cat. no. BOD 20. Canberra: AIHW; 2019. Available from: <https://www.aihw.gov.au/getmedia/953dcb20-b369-4c6b-b20f-526bdead14cb/aihw-bod-20.pdf.aspx?inline=true>

### Option 3. Nicotine for all human use is included in the Poisons Standard as a prescription only medicine with a requirement for a child resistant closure for the container

186. The third option would, by a decision of the Secretary's delegate under s 52D(2) of the TG Act, make nicotine for all human use (other than in nicotine replacement therapy or tobacco prepared and packed for smoking) a prescription only medicine (that is included in Schedule 4 of the Poisons Standard). It would be available exclusively on prescription by a medical practitioner. The decision would include a requirement for a child resistant closure for the container. The amendment to Schedule 7 is intended to act as a catchall provision, and is unlikely to have application dependent on the amended Schedule 4.

187. The proposed amendment of the current Poison Standard in relation to nicotine is set out in Table 3:

**Table 3: Proposed amendments to the Poisons Standard, against the current provisions**

Location	Current provision	Proposed provision
<b>Schedule 4 Prescription only medicine</b>	NICOTINE in preparations for human therapeutic use <b>except</b> for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.	NICOTINE in preparations for human use <b>except</b> : <ul style="list-style-type: none"> <li>a) in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking; or</li> <li>b) in tobacco prepared and packed for smoking</li> </ul>
<b>Schedule 6 Poison</b>	NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.	
<b>Schedule 7 Dangerous poison</b>	NICOTINE <b>except</b> : <ul style="list-style-type: none"> <li>a) when included in Schedule 6;</li> <li>b) in preparations for human therapeutic use; or</li> <li>c) in tobacco prepared and packed for smoking.</li> </ul>	NICOTINE <b>except</b> : <ul style="list-style-type: none"> <li>a) when included in Schedule 4;</li> <li>b) in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking</li> <li>c) in tobacco prepared and packed for smoking</li> </ul>
<b>Appendix D, Item 5, Additional controls</b>		Nicotine
<b>Part 2-4 Container to be closed with child resistant closure</b>		Required child resistant closure for the container.

## Rationale for the proposed changes

188. The proposed Schedule 4 entry will capture nicotine when prepared for use in e-cigarettes, e-juice, heat-not-burn tobacco products, chewing tobacco, snuff and other novel nicotine products. There is presently no heat-not-burn tobacco product in Australia. The present market for chewing tobacco and snuff is insufficient to quantify in a regulatory impact assessment. Accordingly, this RIS assesses the regulatory impact of option 3 on e-cigarettes containing nicotine and the nicotine alone with relevant consequential impacts.
189. Restrictions on the availability of e-cigarettes would mitigate the potential uptake of smoking in 'ever users', particularly young adults who would otherwise be at low risk of initiating nicotine addiction. Nicotine containing e-cigarettes can only be imported, under the personal importation scheme in the therapeutic goods framework, in accordance with a prescription from a medical practitioner. The regulatory lacuna between Commonwealth and state and territory law would be filled.
190. The inclusion of nicotine in Schedule 4 would require a medical practitioner to make an informed decision, taking into account the risks of nicotine, on whether it is in the patient's best interest to prescribe e-cigarettes as a smoking cessation aid or higher risk novel nicotine delivery preparations. The requirement for a prescription provides an opportunity for a medical practitioner to assess fully a patient's need for e-cigarettes or other novel products containing nicotine. It allows for the provision of advice to patients on all of the potential risks and benefits and how to reduce the risks associated with nicotine use.
191. It would normalise the view that addressing tobacco or nicotine dependence is a medical practitioner's business and indirectly promote cessation treatments to patients and practitioners alike. As patients visit their medical practitioner on average three to four times per year and, generally, regard them as authoritative trustworthy sources of health advice, it also presents a natural opportunity for consideration of options to assist in smoking cessation. The US Surgeon General notes the 2015 'Grade A' recommendation that medical practitioners deliver brief tobacco cessation intervention: 'Even brief (less than 3 minutes) advice from a physician improves cessation rates'<sup>109</sup> and is highly cost effective.<sup>110</sup> The 5As method is the gold standard for delivering this intervention, effective in increasing tobacco cessation and quit attempts among patients as well as increasing engagement in other empirically validated cessation treatments.<sup>111</sup> Making the medical practitioner the port through which a person might access a nicotine containing e-cigarette might also improve the sometimes-haphazard implementation of the 5As method.<sup>112</sup> There is a reasonable argument that this option, with the support provided by a medical practitioner, is most akin

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<sup>109</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>110</sup> M V Maciosek, A LaFrance, S D Dehmer, D A McGree, T J Flottemesh, Z Xu, L Solberg, Updated priorities among effective clinical preventive services *Ann Fam Med* 2017 Jan; 15(1):14-22.

doi: 10.1370/afm.2017. Available from: <https://pubmed.ncbi.nlm.nih.gov/28376457/>

<sup>111</sup> Ibid

<sup>112</sup> Ibid

to the circumstances of the randomised control trial in relation to which it was found that e-cigarettes were an effective smoking cessation tool.

192. Community pharmacists responsible for dispensing prescription medicines may also provide appropriate support.
193. Medical intervention may involve a discussion on what NRT is most suitable for people living with young children and how to use liquid nicotine safely.
194. Further, the RACGP guidelines stipulate that nicotine-containing e-cigarettes are not first-line treatments for smoking cessation and the strongest evidence base for efficacy and safety is for currently approved pharmacological therapies combined with behavioural support. The RACGP guidelines also state that nicotine containing e-cigarettes may be a reasonable intervention for individuals who have failed to achieve smoking cessation with approved pharmacotherapies, but remain motivated to quit smoking and have raised e-cigarette usage with their healthcare practitioner.
195. Although users may express their desire to use e-cigarettes as a long-term substitute for smoking rather than a NRT or other measure and to do so without medical supervision the potential harmful impacts of long-term use of e-cigarettes containing nicotine indicates their use for short-term duration and only under medical supervision for smoking cessation.
196. Further, it is true that there is a perception of inconvenience of having to make, and attend, an appointment for a consultation with a doctor for those who presently use nicotine e-cigarettes. Nevertheless, the frequency with which the annual average Australian patient (notably those who are smokers) attends a consultation with their medical practitioner and evidence that it presents the best opportunity for a patient to successfully stop smoking does not sufficiently detract from the anticipated benefits of the requirement for medical supervision to justify departure from it.
197. Finally, the pharmacokinetics of nicotine delivery by e-cigarettes are more likely to be comparable to combustible cigarettes, with rapid nicotine absorption and delivery to the brain, thereby potentially increasing their appeal to smokers trying to stop smoking; their appeal may also be enhanced by their similar method of use and sensation in the mouth and lungs.<sup>113</sup> This is consistent with the evidence given to the Senate Select Committee on Tobacco Harm Reduction by one of three e-cigarette users, Mrs Lennon.

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<sup>113</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>; Banks E, Beckwith K and Joshy G. Summary report on use of e-cigarettes and relation to tobacco smoking uptake and cessation, relevant to the Australian context. Acton ACT: Australian National University, Research School of Population Health, National Centre for Epidemiology & Population Health; 2020. Available from: <https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf>; O'Brien D, Long J, Lee C, McCarthy A and Quigley J. Electronic cigarette use and tobacco cigarette smoking initiation in adolescents: An evidence review. Dublin: Health Research Board May 2020. Available from: [https://www.drugsandalcohol.ie/33170/1/Electronic\\_cigarette\\_use\\_and\\_smoking\\_initiation\\_in\\_adolescents.pdf](https://www.drugsandalcohol.ie/33170/1/Electronic_cigarette_use_and_smoking_initiation_in_adolescents.pdf).



198. Nevertheless, the available evidence does not support that e-cigarettes are a safer alternative to smoking cessation aids currently available and there is currently insufficient evidence, at a population level, to conclude whether e-cigarettes can benefit smokers in quitting. In this regard, the inclusion of a poison in a Schedule indicates the degree of control required if it is marketed. It does not indicate that the poison is available; nor that it has been approved or is efficacious for any use that may be specified in a Schedule; nor does it negate any obligation for registration of a therapeutic good containing that poison.
199. Inclusion of nicotine, when in Schedule 4 medicines, in item 5 of Appendix D of the current Poison Standard would ensure that possession of Schedule 4 preparations containing nicotine must be in accordance with a legal prescription. The inclusion of a child resistant closure requirement has the effect that the risk of poisoning, with the advice from medical practitioners about appropriate storage of a medicine, is more or less eliminated.

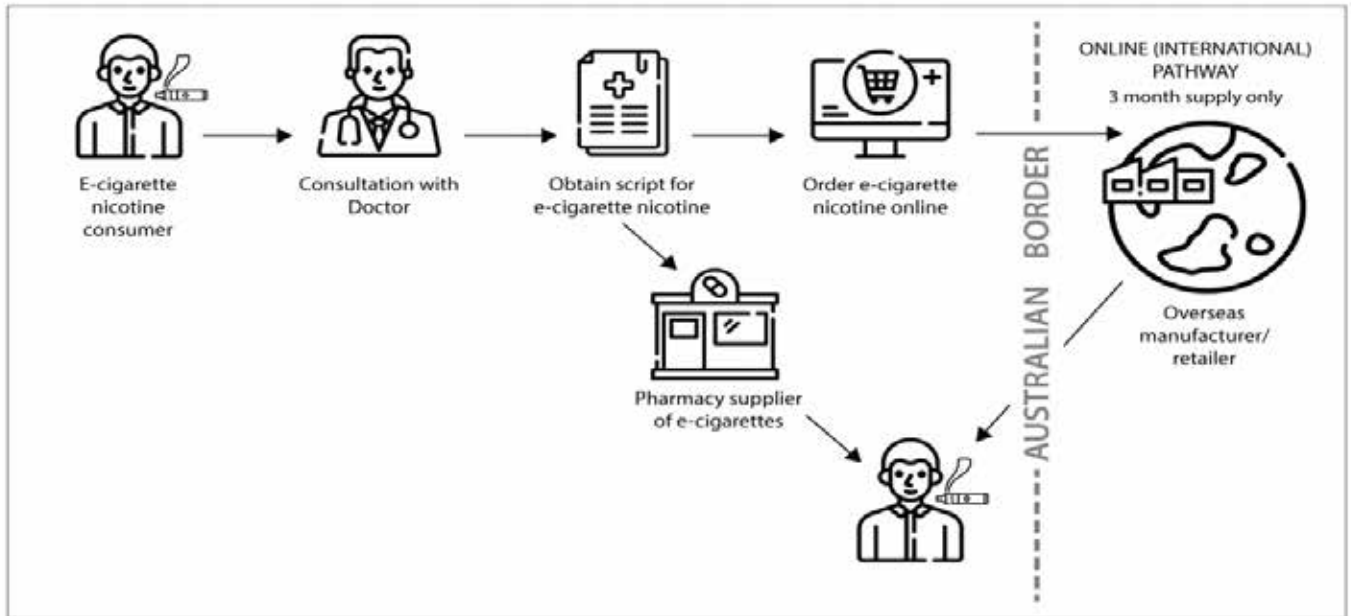
### What the scheduling decision would mean for consumers

**Table 4: Access schemes for nicotine-containing e-cigarettes for ALL human uses following proposed amendments to the Poisons Standard**

<b>NICOTINE-CONTAINING E-CIGARETTES FOR HUMAN USE</b>	
<b>Intended use</b>	<b>ALL human use (Schedule 4, prescription only medicine)</b>
<b>Mode of access</b>	Nicotine-containing e-cigarettes are a medicine, available by prescription only; a child resistant closure would be mandated for the container.
	Obtain prescription from medical practitioner
<b>Safeguards</b>	Patient must be smoker, intending to quit
<b>Importation and use</b>	Lawful personal importation under the personal importation scheme
	Lawful purchase from a pharmacist
	Lawful possession and use

200. The effect on consumers of including nicotine for all human use as a prescription only medicine is captured in the figure below which also includes steps that would lead up to dispensing the prescription:

**Figure 3.1: Flow chart depicting steps to filling a prescription for e-cigarettes**



201. To obtain nicotine containing e-cigarettes patients wanting to use them as an aid to smoking cessation would need to attend a consultation with their medical practitioner. Users would need to first familiarise themselves with the potential impacts of the clarification of the entry of nicotine in the Poisons Standard, which Noetic has estimated would be 2 minutes a person for the total awareness population of 418,000. That population has been arrived at by using Institute of Health and Welfare National Drug Strategy Household Survey for 2019 (this is the total of 'youth', 'smokers' and 'former smokers' who use e-cigarettes at least monthly). The overall regulatory 'familiarisation' compliance cost for this combined group is estimated by Noetic to be \$445,867.

202. Anyone (whether an adolescent, young adult or otherwise) wanting to use nicotine containing e-cigarettes for a non-medical purpose would not be able to *lawfully* secure access by either domestic or international supply. As noted in table 8 in Annexure A comprehensively setting out the regulatory impacts on different cohorts, to seek to do so would expose a person to committing a criminal offence or civil penalty contravention.

203. Noetic has assumed that patients would first need to identify a medical practitioner willing to prescribe nicotine. Identification of medical practitioners by their prescribing behaviour, rather than by their assistance to patients to stop smoking, risks directing patients to medical practitioners who are ardent supporters of nicotine containing e-cigarettes. By their predisposition to prescribing e-cigarettes such practitioners may not carry out an holistic consideration of the patient. In this regard, there is a body of evidence showing that relying entirely on the discretion and prescribing practices of individual doctors does not necessarily protect public health and safety from the overuse and harms of

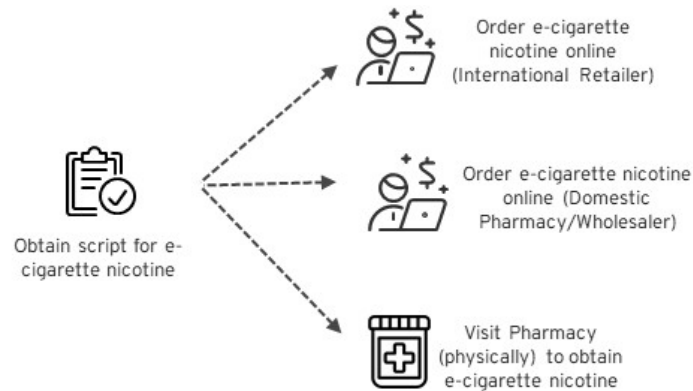
Schedule 4 substances.<sup>114</sup> This applies to both medicines and poisons.<sup>115</sup> These are issues for which the Medical Board of Australia assumes regulatory responsibility in accordance with the Health Practitioner Regulation National Law applied by each state and territory.

204. Nevertheless, Noetic has assumed, in the first year of the scheduling change, a 2-minute online search for relevant medical practitioners performed by 344,197 patients.
205. With the increasing popularity among patients of virtual consultations, it is expected that these will increase over the 10-year life of the regulatory costing period. Noetic has estimated that 20% of initial additional GP visits will be virtual with a yearly growth rate of 10%.
206. This would avoid not only the commute time to an in-person consultation, estimated by Noetic to be an average of 30 minutes; it would also avoid the average waiting time in the GP surgery of 30 minutes. Noetic estimates that, for those visits not costed (those attending an additional two or more consultations per year) an initial visit will be 5 minutes additional to all subsequent visits. A virtual consultation would also facilitate visits to medical practitioners by those in rural or remote communities.
207. Whether a consultation with the medical practitioner is virtual or in-person, a person would be required to book that consultation which Noetic estimates to be 2 minutes.
208. Noetic has therefore estimated that the total effort to make a booking and attend a consultation is 77 minutes for an in person consultation and 17 minutes for a virtual consultation.
209. The purpose of this consultation is to ensure that the use of e-cigarette nicotine as a second-line measure to aid smoking cessation is supervised by a doctor.
210. As captured by the following figure from Noetic, a prescription for nicotine containing e-cigarettes may only be lawfully given by either:
- a medical practitioner authorised by the TGA as an Authorised Prescriber (see Annexure B for an explanation of this scheme);
  - a medical practitioner with TGA approval under the SAS B scheme (see Annexure B for an explanation of this scheme);
  - a medical practitioner who is willing to prescribe e-cigarette nicotine for a patient to import under the personal importation scheme provided for under the TG Act. The 'personal importation scheme' allows a person to order online from their usual supplier 3 months' supply of e-cigarettes containing nicotine and a maximum amount of 15 months' supply in 12 months. A prescription is mandatory to support lawful importation.

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<sup>114</sup> Australian Commission on Safety and Quality in Healthcare, Literature Review: Medication Safety in Australia, 2013

<sup>115</sup> Huyns, Cairns, Brown et al, Patterns of poisoning exposure at different ages: the 2015 annual report of the Australian Poisons Information Centres, Medical Journal of Australia, July 2018

**Figure 3.2: Flow chart depicting how a patient may fill a prescription for e-cigarettes**

211. Noetic has assumed that the prescription would provide approximately (in accordance with the Pharmacy Board *Guidelines for Dispensing Medicines*) one months' supply, repeated to provide 6 months' therapy in total with prescriptions valid for a maximum 12 months. Accordingly, taking account of doctors' appetite for risk, Noetic has assumed that, on average, GPs will give prescriptions for up to six months. Access to an e-cigarette containing nicotine would therefore require a patient to attend a GP consultation twice yearly. Further, it is likely that for many in the cohort of smokers wanting to stop smoking the GP consultation will be held regardless of the scheduling changes. This would mean that, for those patients otherwise required to visit a doctor twice yearly or more, there is no additional regulatory burden of the scheduling change. For those otherwise not visiting a GP twice each year, there is a requirement for either one or two additional consultations.
212. Noetic estimates the total number of additional visits per year to be 188,000; the total number of future additional in person visits is 695,342 and virtual is 529,143; the total number of future extended visits is 235,159.
213. Because there are likely to be more successful smoking cessation attempts along with disincentives to access nicotine containing e-cigarettes, Noetic has assumed reduced use of nicotine containing e-cigarettes of 10% per year from the second year of the regulatory costing period. In turn, this affects the numbers of medical practitioner consultations.
214. On the basis of these inputs, Noetic has estimated that the overall regulatory compliance cost for smokers to obtain a prescription is, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), \$34,347,175.
215. A patient would be able to fill the prescription, one months' supply at a time by an:
- in person visit to a pharmacy, for which Noetic has estimated travel time of two minutes and in-pharmacy time of five minutes;
  - online purchase from a domestic retailer for which the uploading time for a prescription is estimated by Noetic to be four minutes; or
  - online purchase from an international retailer in accordance with the 'personal importation scheme' for which Noetic advises that there is no additional regulatory impact because the activity does not represent any change to the regulatory baseline (this is currently how Australian users obtain nicotine containing e-cigarettes).

216. Noetic has applied the following analysis to determine the future population demand is:

- first, reduced by those for whom the GP does not prescribe an e-cigarette – that is by 15%;
- second, with the success of the clarification, reduced by 10% per year from the second year of implementation;
- assumed to be met
  - i. 50% by international retailers (noting the ease with which this is presently done and that it attracts no additional regulatory impact);
  - ii. 30% met by domestic retailers (noting the reduced costs associated with the latter) which would take four minutes to execute including the requirement to upload a prescription; and
  - iii. 20% by pharmacies, 30% of visits to which will not be exclusively to purchase e-cigarettes (Noetic refers to the National Drug Research Institute, Curtin University report, *Identifying the Social Costs of Tobacco Use to Australia in 2015/16*).

217. On the basis of these inputs, Noetic has estimated that the overall regulatory compliance cost for smokers to fill a prescription is, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), \$13,926,242.

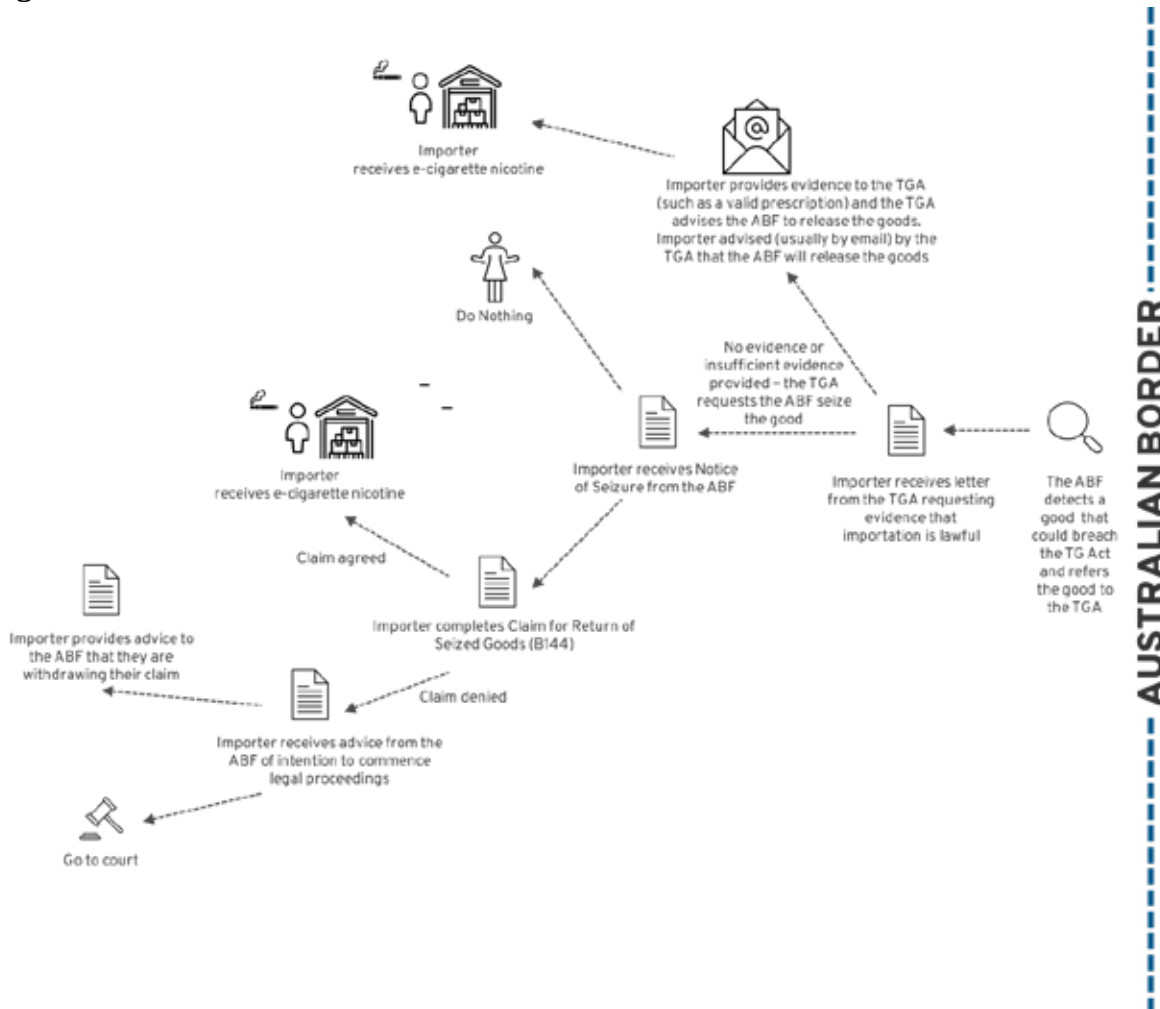
218. The overall 'obtain a prescription' regulatory burden, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework,) is therefore \$48,273,418.

219. The total regulatory burden for smokers of the scheduling clarification, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), is \$48,719,284.

220. If the package containing the e-cigarette nicotine is intercepted at the border by the Australian Border Force (ABF), the importer must provide a valid prescription/doctor's letter to justify return of the goods, or face prosecution or civil penalty contravention.

221. The process is accurately captured by the 'Border seizure flowchart' on the following page prepared by Noetic:

Figure 3.3: Border seizure flowchart



222. Although the risk of commission of a criminal offence or civil penalty contravention is likely to be highly effective in ensuring, in the case for smokers and former smokers, purchase with a prescription, it may not be 100% effective. In particular, a person may, despite the risk of committing a criminal offence or civil penalty contravention, order nicotine containing e-cigarettes from an international retailer without a prescription, chancing detection by the ABF. Particularly, having regard to the fact that this is the case under the personal importation scheme for any prescription medicine and that the individual risks conviction, little weight is given to the risk of unlawful behaviour.

223. Further, Noetic has been unable to advise the likely detection rate at the border for e-cigarettes legally imported to Australia under the personal importation scheme. Consistent with its usual practice, the ABF would refer the package to the TGA for interaction with the importer to determine the lawfulness of the import by provision of a valid prescription (this may also involve the TGA testing for the presence of nicotine). If the importer does not provide the prescription, the importer will then need to give to the ABF contact information and seizure details (from the Notice of Seizure) and a short statement pertaining to the holding of a valid prescription (and likely a copy of the prescription) on the 'Claim for return of seized goods' (Form B144). Noetic has assessed this should take no more than five minutes to complete and return to the ABF. Accordingly, Noetic does not

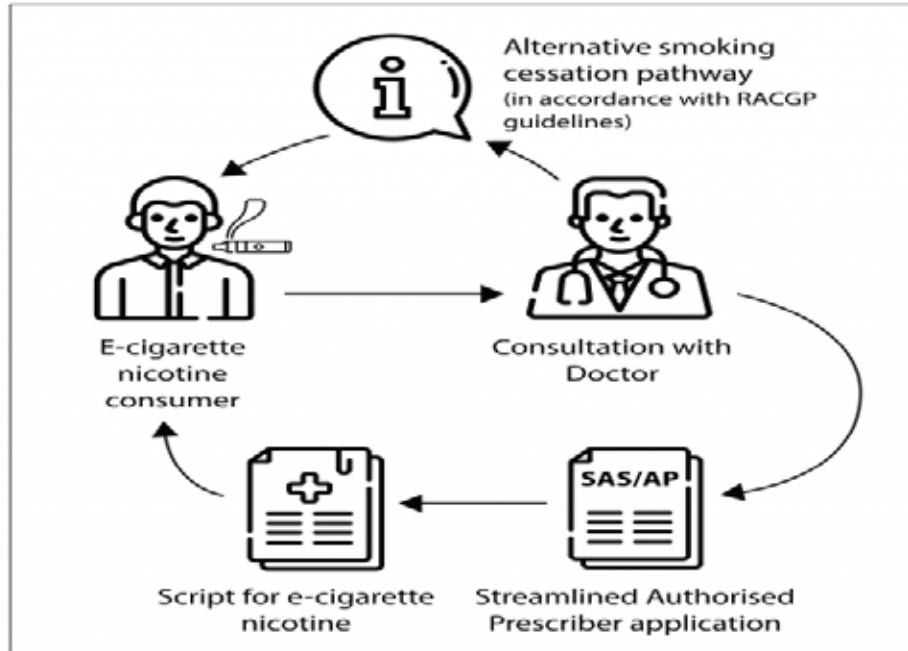
consider any arising regulatory burden likely to be material to the overall regulatory costing.

224. Finally, a couple of other observations. First, there is no reason to anticipate that filling a prescription would incur cost additional to what a consumer presently pays for the product. If any change could be reasonably posited, it would be a reduction in cost arising from being able to source the product locally and thereby avoiding the requirement to incur international freight costs. Indeed, Noetic advises that ‘the proposed regulatory change will upset existing market dynamic and will likely create favourable market opportunities for domestic pharmacies to potentially undercut overseas retailers in both price as well as shipping times.’
225. Second, the likely exclusion of nicotine containing e-cigarettes from being entered on the Pharmaceutical Benefits Scheme Schedule due to concerns regarding its effectiveness for cessation and cost effectiveness, is unlikely to have any particular cost impact for the consumer – there is no likely subsidy to the market price, the best predictor of which is today’s price.

### What the scheduling decision would mean for medical practitioners

226. The effect on medical practitioners of including nicotine for all human use as a prescription only medicine is captured in the following figure.

**Figure 3.4: Flow chart depicting steps to prescribing e-cigarettes**



227. Because there are no nicotine containing e-cigarettes entered on the ARTG, it is anticipated that, at least for the first year of the scheduling change, some medical practitioners would need to seek approval to supply by way of the TGA’s Special Access Scheme B (SAS B) and Authorised Prescriber (AP) schemes (as explained in Annexure B).
228. As noted under the section dealing with the implications of Option 3 for consumers, the other lawful means for securing access to an unapproved medicine, the personal

importation scheme, does not require any additional steps be taken by the medical practitioner before prescribing nicotine containing e-cigarettes.

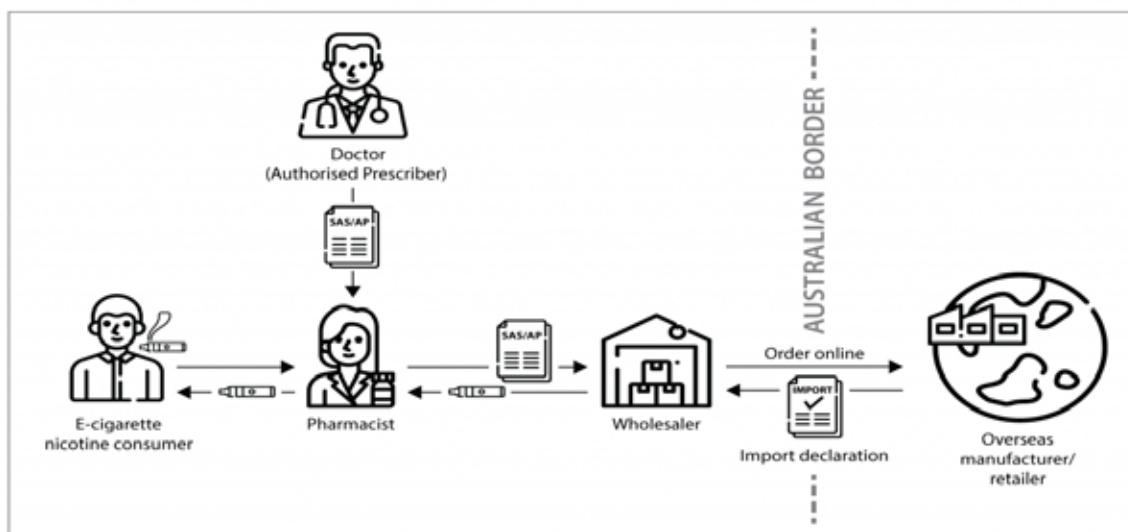
229. Noting that the TGA has received expressions of interest from three potential applicants for registration, there is at least some prospect of a product being entered on the ARTG in the second year of the scheduling change, which would remove any requirement for a medical practitioner to supply by these alternative pathways.
230. Medical practitioners are eligible for the AP scheme – to prescribe nicotine as an aid to stop smoking - without the usual requirement for ethics committee approval. During the five-year-authorisation period, no further applications or permissions are required. Only a prescriber's name and AHPRA number is required to be filled into a simple online form, which is available on the TGA website. The AP is required to report six monthly to the TGA detailing new and repeat patients.
231. For the first year in which there will be no e-cigarette containing nicotine entered on the ARTG, medical practitioners will be required to acquaint themselves with the process requirements of being an Authorised Prescriber.
232. Noetic has estimated that this awareness activity will take 2 minutes per GP. Noetic has applied this to the Grattan Institute's estimate of 7,000 clinics in Australia in 2018, only 50% of which would likely seek AP authorisation from the TGA. This arises because of the likelihood of 50% of all patients using the personal importation scheme to secure supply of nicotine containing e-cigarettes.
233. Noetic has further estimated that to become an AP would require:
- For those not familiar with the scheme:
    - i. an estimated 10 minutes reading time to understand the application process and ongoing reporting requirements;
    - ii. 5 minutes to establish an account with the TGA and 5 minutes to apply to become an AP
  - For those familiar with the scheme,
    - i. 30 seconds to login to an existing account; and
    - ii. 5 minutes to apply to become an AP.
234. The six monthly reporting obligation to the TGA detailing new and repeat patients is estimated to take 10 minutes per report.
235. For future population considerations, noting that not all access to e-cigarettes would require a GP to have AP authorisation from the TGA, Noetic has estimated that 50% of clinics will apply to have a single AP, with 80% of those being familiar with the AP scheme and therefore requiring to log in and complete the AP application (5.5 minutes); 20% require 20 minutes.
236. Accordingly, considering these inputs, Noetic has estimated that the overall 'AP' regulatory burden is, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), \$244,292.



237. Medical practitioners who are not APs will be required to:
- For non-familiar medical practitioners, acquaint themselves with the SAS B scheme, which Noetic estimates, is reading time of 10 minutes.
  - apply for SAS B approval which Noetic estimates requires:
    - i. 5 minutes to establish an account with the TGA (for non-familiar medical practitioners) and 30 seconds to log in to an existing account; and
    - ii. 5 minutes to apply for SAS B approval per patient.
238. For future population considerations, Noetic has estimated 5% of total GPs are not familiar with the SAS B requirements and may need to do additional reading and create a new account, amounting to 15 minutes per doctor. 5% of total consultations will require a doctor to carry out SAS B administration (at 5.5 minutes per patient submission).
239. On the basis of these inputs, Noetic has estimated that the overall 'SAS B' regulatory burden is, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), \$534,327.
240. The total regulatory burden for medical practitioners is therefore estimated, over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework), as \$778,619.
241. One final observation, as the regulatory change would not affect how a medical practitioner carries out the business of attending to patients, there is no anticipated impact on the medical benefits scheme.

### **What the scheduling decision would mean for pharmacists**

242. The effect on pharmacists of including nicotine for all human use as a prescription only medicine is captured in the figure on the following page.

**Figure 3.5: Flow chart depicting steps to obtaining e-cigarettes to aid smoking cessation**

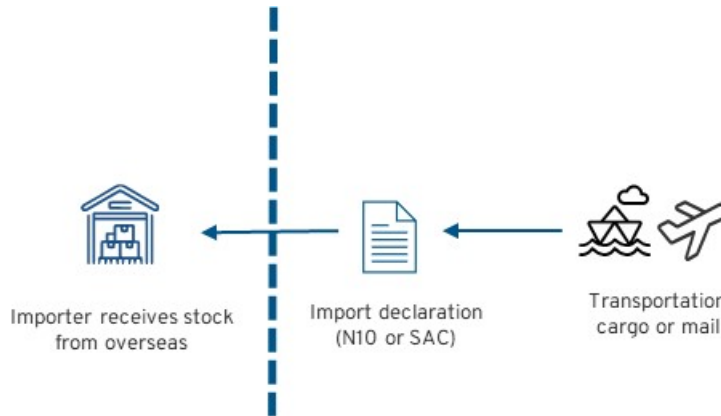
243. Under the proposed amendment, pharmacists would be able to dispense a prescription for a nicotine containing e-cigarette with evidence of a SAS Category B or AP approval. The usual NRTs (including sprays, patches, lozenges and chews), available without prescription from pharmacies and some retail outlets, would not be affected by the proposed decision.
244. Pharmacists would also be able to extemporaneously compound in the usual way.
245. In practice, a pharmacy wholesaler would apply for an import permit under either import declaration (N10) or self-assessed clearance (SAC) declaration.
246. Accordingly, Option 3 presents no additional regulatory burden for pharmacists.

### What the scheduling decision would mean for retailers and wholesalers

247. As the sale of nicotine containing e-cigarettes is presently unlawful in every state and territory it is not anticipated that there will be any impact of the scheduling decision on retailers of non-nicotine containing e-cigarettes and the devices. As there is presently no interest from pharmacies in separately retailing e-liquid flavours to mix with nicotine and devices current retailers of those products will continue to maintain their share of these markets. There does not seem to be anything on the face of Option 3 which would suggest it would have any particular kind of impact on this market. What is prescribed would be driven by consumer preference with clinical judgement brought to bear. This kind of response is not new; it is intrinsically linked to the usual forces which affect the development of any market. It is not possible, and therefore not appropriate, for the RIS to second guess what might prove to be the outcome. Sufficient demand by users for refillable e-cigarettes will ensure retailers maintain their current business model. The reasonably recent arrival of nicotine containing pods already threatens this business model.
248. Noetic advises that there is no regulatory burden associated with the proposed inclusion in the scheduling decision of the requirement for child resistant closures for e-liquids. This is on the basis of used information given to it by the Department about regulatory requirements in the US and UK requiring child resistant closures for e-liquids for use in e-cigarettes, the anticipated introduction of such a requirement in New Zealand (consistent with what is set out in paragraph [132] and an assumed a consistent regulatory response by

Malaysia. The effect on wholesalers of including nicotine for all human use as a prescription only medicine is captured in the figure below.

**Figure 3.6: Flow chart depicting steps to wholesale importation of e-cigarettes**



249. Future importers of e-cigarette nicotine will likely already be involved with the importation of pharmaceuticals and will therefore likely have in place business-to-business data interchange software to largely automate the production of the required importation documentation (as explained by Noetic). That is, their stock management system will provide the necessary details to their customs broker/or via an API with ICS to complete the importation documentation. Thus, this activity does not represent a material burden and Noetic has not included it in the regulatory costing:

250. A detailed assessment by cohort of the impact of including nicotine for all human use in Schedule 4 of the Poisons Standard is set out in table 8, Option 3 Nicotine for human use is prescription only, in Annexure A. Noetic's regulatory burden costing is at Annexure D. That analysis is captured at a high level immediately below, followed by a summary assessment.

### **Analysis of impact of Option 3: Nicotine for human use available on prescription only; mandated child resistant closure**

251. The regulatory impost and burden on various cohorts from Option 3 is clearly articulated by Noetic, with a total assessment of \$49,784,877 over the default 10 year period (in accordance with the Australian Government's Regulatory Burden Measurement Framework) as follows:

- On adolescents and young adults to familiarise themselves with the regulatory changes (Noetic's assessment of the cost of familiarisation of all cohorts = \$630,355);
- On smokers and former smokers to familiarise themselves with the regulatory changes (costing noted above), and for e-cigarette users (daily or weekly) to consult their medical practitioner (where they would not normally attend 2 such consultations per year) and, if prescribed nicotine containing e-cigarettes to fill the prescription (Noetic's assessment = \$48,273,417);

- On medical practitioners to familiarise themselves with the regulatory changes, at least for the first year post the reform, to become an AP or to receive TGA approval for access under the SAS B scheme before prescribing nicotine containing e-cigarettes (Noetic's assessment = \$778,619); and
  - On wholesalers to familiarise themselves with the regulatory changes (costing noted above);
  - For a sponsor to apply to register a nicotine containing e-cigarette (Noetic's assessment = \$102,486)
252. The average annual regulatory burden over the 10-year regulatory period is \$4.98 million.
253. There are also, as follows, other alleged behavioural imposts from Option 3. As also explained, each issue is also either adequately anticipated by the scheduling decision or the 'What this means for you' education measures proposed after it is made (see paragraph [259]).
254. First, it is alleged that it demeans, if not completely dismisses, the thousands of success stories of the use of nicotine containing e-cigarettes to quit smoking recounted in the public submissions to both the Delegate's invitation and to the Senate Select Committee on Tobacco Harm Reduction.
- Those stories are not dismissed or demeaned, they are accepted as genuine, heartfelt, real world testimonials of individuals who have worked to give up an addiction.
  - The complaint, however, misreads the implications of the decision. Access to nicotine containing e-cigarettes is not 'banned'. It remains available for those for whom a medical practitioner, *in consultation with their patient*, prescribes it. Further, as Professor Chapman, said in his opening statement to the Senate Select Committee on Tobacco Harm Reduction 'we don't assess the effectiveness of anything by considering only those who had a positive outcome. That's why people who swear, for example, that they can drive perfectly well after drinking is not strong evidence that they actually can.'
255. Second, it removes, from those wishing to use nicotine containing e-cigarettes as an ever user or as a long-term substitute for smoking rather than an NRT or other measure without medical supervision, the freedom to choose.
- Such an allegation gives no weight to the risk of the gateway effect to smoking and nicotine addiction for ever users. Further, for those presently using nicotine containing e-cigarettes, it discounts the precautionary principle including the evidence that medical supervision is appropriate for a product for which the long-term harms are not known. It fails to account for alternative smoking cessation tools including currently available medicines for which the long-term safety effects are known, to supporting only short-term use and to the long-term goal of transitioning off nicotine completely. It gives no weight at all to the potential cost to public health from poor population health outcomes.

256. Third, there is also the perception of causing an inconvenience of having to make, and attend, an appointment for a consultation with a medical practitioner with the risk of undermining any chance smokers will have to stop smoking with appropriate support. This was, for example, the tenor of the evidence to the Senate Select Committee on Tobacco Harm Reduction of two of the three e-cigarette users, Mss Gorman and Lennon. In the same session, however, Mr Reid, the third user, testified to the ease with which he accessed e-cigarettes with the support of a prescription: 'It was not cumbersome; for me it was quite easy'. Whilst not entirely clear, Mr Reid's subsequent disavowal of support for the 'prescription model' appears to have been made on the basis of a misunderstanding that this equated to the proposed inclusion of vaporiser nicotine in the *Customs (Prohibited Imports) Regulations 1956* as a prohibited import.
257. There is a risk that the requirement for a prescription to secure access to nicotine containing e-cigarettes might incentivise patients who might otherwise want to use nicotine containing e-cigarettes and who are not willing to participate in a medical practitioner's consultation or have no legitimate basis to persuade a medical practitioner to prescribe the product, to seek out other nicotine containing products. In his evidence before the Senate Select Committee on Tobacco Harm Reduction Dr Mendelsohn, Board Member, Australian Tobacco Harm Reduction Association, referred to a survey of over 7,000 vapers of which 42 per cent claimed 'if they couldn't get their liquid nicotine, they would go back to smoking and 37 per cent said they would go to the black market'. Dr Mendelsohn did not specify the circumstances of the survey.
258. The strength of the perception and the follow on effect referred to in the previous two paragraphs is undermined by the frequency with which the annual average Australian patient (notably those for which smoking related illnesses necessitates) attends a consultation with their medical practitioner coupled with evidence that it presents the best opportunity for a patient to successfully stop smoking. Further, as it remains lawful to use the personal importation scheme (to import up to 3 months' supply at any one time) there is no required change to the avenue used for securing supply. However, alternative access options may be attractive.
259. These voiced concerns serve to emphasise the importance of the Department's proposed 'What this means for you' education campaign for those affected by the scheduling decision, e-cigarette users, medical practitioners, pharmacists and wholesalers and retailers. The campaign is *not* a public awareness campaign of the kind described at paragraph [168]. Rather, it will explain the implications of the decision, building on the materials already published by the Department contemporaneously with the Delegate's interim decision on 22 September 2020. Among other things, it will address the expressed 'inconvenience' concern to fully inform smokers about options for them to stop smoking including with the support of a medical practitioner with, or without, the use of nicotine containing e-cigarettes. The objective will be to dispel the perception of a hurdle – to quitting.
260. Fourth, it may not be quite correct to say that there is an impost on the relatively small group of people, described by Professor Allan, President Royal Australian and New Zealand College of Psychiatrists, in his evidence to the Senate Select Committee on Tobacco Harm Reduction as the 'forgotten people'. However, for this group, it is widely accepted that mental health issues cause them not to present to a GP, not to engage with the health system. The proposed decision may not assist this group to quit smoking. There is a risk the group will be further marginalised.

- Nevertheless, as Professor Allan advised the Committee, this would not justify not pursuing the scheduling decision and treating nicotine containing e-cigarettes as a consumer good.<sup>116</sup> There may be other means by which this group might be reached to support them to quit. The Department proposes to consult with addiction specialists to understand what, if anything, might be done to address this issue.

261. Fifth, for medical practitioners and pharmacists, - as noted by the Royal Australian College of Physicians, the AMA, the RACGP, the Society of Hospital Pharmacists Australia (the SHPA), the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia, the availability of nicotine containing e-cigarettes on prescription will require health practitioners to understand more about the product, its reliability and the reliability of sources. There is a concern about substandard or counterfeit products. The SHPA went so far as to advise that it would be reasonable to limit the importation of liquid nicotine containing products into Australia to countries such as the United Kingdom and New Zealand. Such a choice remains available and consistent with the scheduling decision. A trio of academics from Wollongong University (Drs Moller and Kelso and Professor Jones) which has been studying electronic cigarette fluids and their content for the past two years recommend restrictions on concentration of nicotine and maximum container volumes and compulsory labelling requirements.

262. Health practitioners will need to know the effective absorption from different devices and education on how to taper off those products. Medical practitioners may be concerned about the role that they will assume, when there is no nicotine containing e-cigarette entered on the ARTG, as 'gatekeeper'.

- Working with these peak bodies, the Department will consider the appropriate measures to meet health practitioners concerns. This would be addressed by the 'What this means for you' education campaign and consideration would be given to the preparation of clinical guidelines. The Department defers to the expertise of medical practitioners and pharmacists. The Department appreciates they are skilled practitioners; use of unapproved medicines is not an unknown. Access is also not necessarily the outcome of consultation with a patient. The benefit will be that both the user and the health practitioner will know what the user is ingesting and that users might overcome their nicotine addiction.

263. Accordingly, neither the regulatory burden nor the alleged impost on behaviours would suggest that the scheduling decision is inappropriate.

264. Finally, as is usual with regulatory reform of any kind, there is a risk of unintended consequences of Option 3 including:

- an increase in black market trade in nicotine containing e-cigarettes; and

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<sup>116</sup>[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Tobacco\\_Harm\\_Reduction/TobaccoHarmReduction/Public\\_Hearings](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Tobacco_Harm_Reduction/TobaccoHarmReduction/Public_Hearings)

- promotion of sub-standard or counterfeit nicotine containing e-cigarettes or product with potentially lower quality or contaminants.

265. The proposed standard for nicotine containing e-cigarettes should incentivise the purchase of goods known to adhere to the relevant standard including those emanating from countries for which standards are already in existence or mooted. Further, the risks referred to exist for any prescription only medicine. They are ones for which the TGA, working with its state and territory counterparts, is the responsible regulator. In turn, the TGA works collaboratively with the ABF. For example, in July this year, the TGA issued a safety advisory alert of counterfeit alprazolam 2mg tablets and counterfeit Kalma 2 tablets (a genuine Australian product). The alert included information for consumers on how to identify the difference between the counterfeit and the 'genuine' medicine. It also notes that the TGA was working with the ABF to help stop any future shipments of counterfeit Alprazolam entering Australia.<sup>117</sup>

266. Further, applying the first criteria for assessing the regulatory options demonstrates its anticipated superior achievement, to Option 2, in meeting the three regulatory objectives. This is so even accounting for smokers who may find the increased barriers to access to smoking cessation measures insurmountable; as well as for those ever users who may wish to risk commission of a criminal offence or contravention of a civil penalty provision and to continue to source nicotine containing e-cigarettes unlawfully.

267. Indeed, when appropriate consideration is given to the gravity of:

- the evidence that tobacco use is associated with co-morbidities including that it remains a leading cause of preventable death and disability in Australia (estimating to kill 21,000 Australians in 2015) along with the present overall social (including health) costs of tobacco use in Australia estimated at \$137 billion in 2015-16;
- the risk of the gateway effect on ever users and particularly adolescents and young adults of use of e-cigarettes to smoking; and
- the risk of accidental poisonings by children;

it is apparent that Option 3 is best placed to deliver on the identified regulatory objectives. It is structured to provide the most effective support to a smoker to stop smoking – that is the support from their medical practitioner. An increase in smokers who quit will reduce the impact on the public health system, by what order of magnitude is difficult to assess.

Option 3 includes a clear barrier to access to nicotine containing e-cigarettes by ever users including adolescents and young adults – with the risk of commission of a criminal offence or civil penalty contravention posing a very serious deterrent to attempting access without a prescription (even if not fail proof for those wishing to engage with this risk). Option 3's inclusion of a requirement for all nicotine containing e-cigarettes to include a child resistant

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<sup>117</sup> <https://www.tga.gov.au/alert/counterfeit-alprazolam-2mg-and-kalma-2-tablets>

closure is the optimum that can be achieved to avoid accidental child poisonings by consumption of nicotine.

**Summary of assessment of Option 3: Nicotine for human use available on prescription only; mandated child resistant closure**

268. Having regard to the policy objectives of protection from the 'on-ramp' effect and providing for the 'off-ramp' effect (set out in paragraph [14]), as well as protection of children from accidental poisoning, Option 3 is superior in benefits to Option 2. The superiority of achievement is significant relative to the regulatory impost.



## **Option 4. Inclusion of nicotine in Schedule 4 of the Poisons Standard as a prescription only medicine combined with public awareness campaign**

269. Option 4, a combination of Options 2 and 3, would address the objectives of the regulation with the support of an appropriately targeted public awareness campaign. It would therefore carry the regulatory burden associated with Option 3 and the benefits noted for both – with the investment of public monies the difference between the Option 3 and Option 4. This option is therefore rightly considered attractive and possibly superior to any other Option.
270. However, supplementing Option 3 with a public awareness programme to support the inhibition of the uptake of use of nicotine containing e-cigarettes and how to reduce the risk of accidental consumption of nicotine is almost entirely unnecessary – insofar as delivering on two of the three regulatory objectives is concerned. This is because that Option is, subject to the unlawful behaviour of ever users in seeking to access nicotine containing e-cigarettes without a prescription, clearly designed to deliver on the ‘on ramp’ regulatory objective. Only a complete prohibition on availability of these products would be more likely to deliver on that objective. The same can be said in relation to accidental child poisonings; there is very likely no measure additional to the child resistant closure requirement accompanied by sound advice from health care professionals that could secure this regulatory objective.
271. The situation is arguably more complex for the regulatory objective for smokers / former-smokers population. As earlier mentioned Option 3 includes a public ‘What this means for you’ education programme targeted at addressing the issues affected stakeholders indicated would impact implementation. Whether a public awareness programme of the kind mentioned in paragraph [168] would, by being implemented contemporaneously with Option 3, necessarily deliver the best long term outcome requires consideration. It becomes a question of timing.
272. Reflecting its proposed coupling with Option 3, the following discussion is more expansive than that presented in Option 2 where the fundamental weakness of the public awareness campaign alone was that it did not address the root cause of the problem – the regulatory lacuna between Commonwealth and state and territory regulation. This point remains pertinent; that the campaign is not the panacea. As explained, that is Option 3.
273. It is true that, particularly having regard to the past success of public awareness campaigns in getting smokers to quit, there is likely to be benefit in such a campaign. For example, an assessment of phase one of the National Tobacco Campaign, which ran from June to November 1997, at a cost of \$9 million and a reduced smoking prevalence by 1.4% demonstrated that the NTC was unequivocally cost-effective. The relevant ‘quit benefits model’ predicted that the NTC avoided over 32,000 cases of chronic obstructive pulmonary disease (COPD), 11 000 cases of acute myocardial infarction (AMI), 10 000 cases of lung cancer, and 2500 cases of stroke. It also predicted prevention of around 55 000 deaths,

gains of 323 000 life-years and 407,000 quality adjusted life years (QALYs), and healthcare cost savings of \$A740.6 million.<sup>118</sup>

274. Whether these results are indicative of what might be achieved by an equivalent investment more than 20 years later is a moot point, that is, without the benefit of modelling from experts on a particular programme design. The rate of success of the campaign will be a function of the proposed expenditure, more precisely the campaign reach, intensity, duration and message type. Sufficient population exposure, especially for lower socioeconomic status smokers is required to generate appropriate results. Generally, smokers from higher socio economic circumstances are more inclined to be receptive to education awareness campaigns. As a higher proportion of smokers are from lower socio economic groups, an effective population wide level reduction in smokers would require relatively higher numbers of weekly exposure which, in turn, will require a more significant investment. This would also address inequity in smoking prevalence. Further, sustained quit attempts require more than a one off investment, repeated levels of advertising are required throughout the year.

275. Nevertheless, a public awareness campaign targeted at smokers to quit would also achieve possibly superior outcomes to Option 3 alone. It would incur a cost to the Budget in the range between \$10 million to \$40 million per annum, generating increasing degrees of success in encouraging smokers to quit with the increasing size of the investment (see paragraph [182]). On its face, Option 4 appears the preferable option.

276. For the smokers / non-smokers population, there is a need to pause and reflect on this conclusion, particularly relatively weighting the effect Options 3 would have of 'medicalising' nicotine containing e-cigarettes. The US Surgeon General states that 'Even brief (less than 3 minutes) advice from a physician improves cessation rates'<sup>119</sup> and is highly cost effective.<sup>120</sup> The 5As method is the gold standard for delivering this intervention, effective in increasing tobacco cessation and quit attempts among patients as well as increasing engagement in other empirically validated cessation treatments.<sup>121</sup> This method to intervention requires

- **Ask** - Identify and document tobacco use status for every patient at every visit.
- **Advise** - In a clear, strong, and personalized manner, urge every tobacco user to quit.
- **Assess** - Is the tobacco user willing to make a quit attempt at this time?
- **Assist** - For the patient willing to make a quit attempt, use counselling and pharmacotherapy to help him or her quit.

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<sup>118</sup> S F Hurley, J P Matthews, Cost-effectiveness of the Australian National Tobacco Campaign, 2008 Dec;17(6):379-84. doi: 10.1136/tc.2008.025213. Epub 2008 Aug 21.

<sup>119</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>120</sup> M V Maciosek, A LaFrance, S D Dehmer, D A McGree, T J Flottemesh, Z Xu, L Solberg, Updated priorities among effective clinical preventive services Ann Fam Med 2017 Jan; 15(1):14-22.

doi: 10.1370/afm.2017. Available from: <https://pubmed.ncbi.nlm.nih.gov/28376457/>

<sup>121</sup> Ibid

- **Arrange** - Schedule follow-up contact, in person or by telephone, preferably within the first week after the quit date.

277. That the most supportive measure for a person to quit, engagement with a medical practitioner, inheres in Option 3 suggests that whilst there is always more that might be able to be achieved by additional measures, there is a questionable necessity for such measures. The question is even more pertinent when it is understood in the context of the addition of the 'What this means for you' education campaign to which the Department has committed in implementing Option 3 (see the explanation of the content of this education campaign at paragraph 259). On this basis, there is a not unreasonable argument for Option 3 to be allowed to run its course before designing and implementing other supplementary policies.

278. There is also a reasonable argument that longer term superior outcomes are likely if a public awareness campaign is designed with the benefit of the assessed impact of Option 3 (having launched with the benefit of the 'What this means for you' education campaign). That is, that it is reasonable for this to occur before determining the necessity for other measures; particularly those measures which require the allocation of scarce public health funds in the 2021-22 fiscal year..

279. As Dr McRobbie, Professor, National Drug and Alcohol Research Centre, University of New South Wales, noted in his evidence at the 13 November 2020 hearing to the Senate Select Committee on Tobacco Harm Reduction in noting New Zealand's regulatory approach to treat e-cigarettes as a consumer good, 'It will be an interesting natural experiment, perhaps between New Zealand and Australia, to see how things pan out . . '

#### **Summary of assessment of Option 4: Inclusion of nicotine in Schedule 4 of the Poisons Standard as a prescription only medicine combined with public awareness campaign**

280. Option 3 does the 'heavy lifting' to achieve each of the 3 regulatory objectives. There is nothing which would necessarily dictate Option 3 is coupled with a public awareness campaign directed at each of the 'ever users' and smokers / former smokers. This conclusion is made more powerful by reference to the US Surgeon General's statement that 'Even brief (less than 3 minutes) advice from a physician improves cessation rates'<sup>122</sup> and is highly cost effective'. Support from a medical practitioner is the most effective support for a smoker to quit. Accompaniment of the scheduling decision with a 'What this means for you' education campaign means it is not unreasonable for it to be allowed to run its course before designing and implementing other supplementary policies. It is reasonable for this to occur before determining the necessity for other measures particularly those measures which require the allocation of scarce public health funds in the 2021-22 fiscal year.

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<sup>122</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

## Recommended option

281. There are good reasons to reach the view that Option 3 is the preferred option.
282. Option 1, the status quo, would fail to address the objectives of regulation, to balance the objectives of supporting smokers to stop smoking with protecting children and young people from risks associated with the use of nicotine containing e-cigarettes. The status quo also perpetuates the risk of nicotine poisoning of young children. Accordingly, the status quo is given no further consideration.
283. Option 2, a public awareness campaign, would address the *outcome* of the root cause of the problem – the regulatory lacuna between Commonwealth and state and territory law. Evidence of past smoking cessation education campaigns and the lapse of time since the last such campaign in 2012, indicate the Option 2 it is likely to have some success.
284. However, Option 2 would not address the underlying problem. Because the lack of information on the part of users of nicotine containing e-cigarettes is not the root cause of the problem but a symptom of it, a public awareness campaign is not likely the most appropriate response to the identified problem. This option also falls short of being the optimum that could be done to remove the risk of accidental nicotine poisoning of children.
285. Nevertheless, the absence of a regulatory burden associated with Option 2 as advised by Noetic has some attraction (Annexure D).
286. In this regard, Option 3, to include in Schedule 4 of the Poisons Standard nicotine for all human use so that it is a prescription only medicine, compares relatively poorly to Option 2. As follows, Noetic has assessed the total regulatory burden to be \$49,784,877 over the default 10 year period (in accordance with the Australian Government’s Regulatory Burden Measurement Framework):
- On adolescents and young adults to familiarise themselves with the regulatory changes (Noetic’s assessment of the cost of familiarisation of all cohorts = \$630,355);
  - On smokers and former smokers to familiarise themselves with the regulatory changes (costing noted above), and for e-cigarette users (daily or weekly) to consult their medical practitioner (where they would not normally attend 2 such consultations per year) and, if prescribed nicotine containing e-cigarettes to fill the prescription (Noetic’s assessment = \$48,273,417);
  - On medical practitioners to familiarise themselves with the regulatory changes, at least for the first year post the reform, to become an AP or to receive TGA approval for access under the SAS B scheme before prescribing nicotine containing e-cigarettes (Noetic’s assessment = \$778,619); and
  - On wholesalers to familiarise themselves with the regulatory changes (costing noted above);
  - For a sponsor to apply to register a nicotine containing e-cigarette (Noetic’s assessment = \$102,486)

287. Accordingly, the average annual regulatory burden over the 10-year regulatory period is \$4.98 million.
288. It is notable, however, that, insofar as regulatory burden is concerned, Option 3 poses no regulatory burden to any business engaged in lawful retail of non-nicotine containing e-cigarettes and the relevant devices. This is because there is no interest from pharmacies in separately retailing e-liquid flavours to mix with nicotine and devices. Of course, this says nothing about the preference of medical practitioners, working with their patients, to prescribe particular kinds of nicotine containing e-cigarettes – those which would require being refilled or pods. Such behaviour, driven by consumer preference with clinical judgement brought to bear, is intrinsically linked to the usual forces which affect the development of any market. It is not possible, and therefore not appropriate, for the RIS to second guess what might prove to be the outcome. Sufficient demand by users for refillable e-cigarettes will ensure retailers maintain their current business model. The reasonably recent arrival of nicotine containing pods already threatens this business model. There is no reason to doubt that current retailers of devices and flavours will continue to maintain their share of these markets.
289. Option 3 also creates an opportunity for others, notably medical wholesalers and pharmacies to supply nicotine containing e-cigarettes. It also creates an opportunity for a person, likely a business, to apply to register a product on the ARTG.
290. It is otherwise inappropriate to give any weight to any impact on sales, which contravene state and territory laws prohibiting sales of nicotine containing e-cigarettes.
291. Further, in applying the first criterion for assessing the regulatory options, it is apparent that Option 3 demonstrates its anticipated superior achievement to meet the three regulatory objectives. The relatively small cohort of smokers who may find the increased barriers to access to smoking cessation measures insurmountable does not undermine this conclusion. Those ever users who may choose to risk commission of a criminal offence or contravention of a civil penalty provision by sourcing nicotine containing e-cigarettes unlawfully are also likely to be insufficient.
292. Option 3 is structured to provide the most effective support to a smoker to stop smoking – that is the support from their medical practitioner. Option 3 includes a clear barrier to access to nicotine containing e-cigarettes by adolescents and young adults – with the risk of commission of a criminal offence or civil penalty contravention posing a very strong deterrent to attempting access without a prescription. Option 3's inclusion of a requirement for all nicotine containing e-cigarettes to include a child resistant closure is the optimum measure to avoid accidental child poisonings by consumption of nicotine. This is appropriately the case in view of the vulnerability of this population and the risk of death.
293. Indeed, when appropriate consideration is given to the gravity of:
- the evidence that tobacco use is associated with co-morbidities including that it remains a leading cause of preventable death and disability in Australia (estimating to kill 21,000 Australians in 2015) along with the present overall social (including health) costs of tobacco use in Australia estimated at \$137 billion in 2015-16;

- the risk of the gateway effect on adolescents and young adults of use of e-cigarettes to smoking – that a whole new generation risks addiction to nicotine and smoking; and
- the risk of accidental poisonings by children;

it is apparent that Option 3 is best placed to deliver on the identified regulatory objectives.

294. Option 4, a combination of options 2 and 3, would address the objectives of the regulation with the support of an appropriately targeted public awareness campaign and involve the same regulatory burden as Option 3. A carefully designed public awareness campaign would possibly achieve superior outcomes. It would incur a cost to the Budget of between \$10 million and \$40 million. On its face, it appears the preferable option.

295. However, there is a need to pause and reflect on this conclusion, particularly when relatively weighting the effect Options 3 would have of ‘medicalising’ nicotine containing e-cigarettes. The US Surgeon General states that ‘Even brief (less than 3 minutes) advice from a physician improves cessation rates’<sup>123</sup> and is highly cost effective.<sup>124</sup> The 5As method is the gold standard for delivering this intervention, effective in increasing tobacco cessation and quit attempts among patients as well as increasing engagement in other empirically validated cessation treatments.<sup>125</sup> This method to intervention requires

- **Ask** - Identify and document tobacco use status for every patient at every visit.
- **Advise** - In a clear, strong, and personalized manner, urge every tobacco user to quit.
- **Assess** - Is the tobacco user willing to make a quit attempt at this time?
- **Assist** - For the patient willing to make a quit attempt, use counselling and pharmacotherapy to help him or her quit.
- **Arrange** - Schedule follow-up contact, in person or by telephone, preferably within the first week after the quit date.

296. That the most supportive measure for a person to quit, engagement with a medical practitioner, inheres in Option 3 suggests that whilst there is always more that might be able to be achieved by additional measures, there is a questionable necessity for such measures. The question is even more pertinent when it is understood in the context of the addition of the ‘What this means for you’ education campaign to which the Department has committed in implementing Option 3 (see the explanation of the content of this education campaign at paragraph 259). On this basis, there is a not unreasonable argument for Option 3 to be allowed to run its course before designing and implementing other supplementary policies.

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<sup>123</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>124</sup> M V Maciosek, A LaFrance, S D Dehmer, D A McGree, T J Flottemesh, Z Xu, L Solberg, Updated priorities among effective clinical preventive services *Ann Fam Med* 2017 Jan; 15(1):14-22. doi: 10.1370/afm.2017. Available from: <https://pubmed.ncbi.nlm.nih.gov/28376457/>

<sup>125</sup> Ibid

297. There is also a reasonable argument that longer term superior outcomes are likely if a public awareness campaign is designed with the benefit of the assessed impact of Option 3 (having launched with the benefit of the 'What this means for you' education campaign). That is, that it is reasonable for this to occur before determining the necessity for other measures; particularly those measures which require the allocation of scarce public health funds in the 2021-22 fiscal year..
298. Accordingly, pending an assessment of its impact at least 12 months after implementation, the preferred option is Option 3.

## Implementation and evaluation

### Implementation

299. When designing the implementation and considering the transition approach, the Department took the following considerations into account:
- The need to allow reasonable time for persons affected by the proposed scheduling decision to prepare, for example medical practitioners and pharmacists to be able to both lawfully access nicotine containing e-cigarettes for those wishing to use them for smoking cessation purposes and to support the bid to stop smoking.
  - Allowing reasonable time for compliance with a requirement for a nicotine containing e-cigarette and e-liquid refills to include a child resistant closure.
300. The consultation period for this work has already resulted in increased understanding of affected stakeholders.
301. If the Delegate decides to include nicotine for all human use as a prescription only medicine implementation would include the following.

### Preparation of the consolidated Poisons Standard

302. The revised Poisons Standard will be drafted to reflect the proposed amendment to the Poisons Standard. The expected publication on the Federal Register of Legislative Instruments is February 2020 and the amendment's effective date is anticipated to be 1 October 2021.

### Education

303. The implementation of the proposed reforms would require an education effort from the Department in collaboration with affected consumers, key peak bodies representing medical practitioners and pharmacists. To this end, Cancer Australia has been engaged to work with medical practitioners. The TGA will publish guidance material on the TGA website and hold stakeholder workshops/webinars.
304. An education program will be put in place and resources provided to the ABF to allow for faster decision making on products. This should facilitate a greater number of products to be assessed and improve compliance in this area.

## **TGA surveillance program**

305. The TGA will develop an enhanced post market testing laboratory program for e-cigarettes to identify nicotine content and to take regulatory action as required.

## **Evaluation**

306. The purpose of the evaluation will be to assess the impact of the regulatory changes, whether the benefits have been realised, the impact on key stakeholders, and safety of children.
307. Evaluation will begin from the commencement of the amendment to the Poisons Standard and conclude 1 year afterwards.

## **Methods**

308. Methods used for data gathering are likely to include:
- formal and informal engagement with stakeholders through consultation and bi-lateral discussions;
  - analysis of data on numbers of Authorised Prescribers and their twice yearly reports along with a similar exercise for SAS B approvals;
  - consideration of whether there are products entered on the ARTG, noting that they will have been assessed for quality, safety and efficacy;
  - analysis of calls to the state and territory Poisons Information Lines
  - ultimately, consideration of the results of the next National Drug Strategy Household survey from the Australian Institute of Health and Welfare.

## **Stakeholders**

309. Stakeholders that will be consulted as part of the evaluation will include:
- healthcare practitioner associations and peak bodies
  - industry—manufacturers and sponsors
  - consumers
  - healthcare practitioners
  - governments, the Department of Health, states and territories

## **Potential questions**

310. Questions that the evaluation may consider or address include:
- Did the amendment to the Poisons Standard deliver on the three regulatory objectives?
  - What are the rates of use of nicotine containing e-cigarettes by adolescents and young adults as well as smokers or former smokers?
  - What do the reports to the state and territory Poisons Information Lines reveal about accidental nicotine poisonings of children?



- How many nicotine containing e-cigarettes are under evaluation and / or entered on the ARTG?
- Were there any unintended consequences for healthcare practitioners, patients particularly those for whom there is an assessed risk of not engaging with a medical practitioner to support smoking cessation or businesses?
- Did the regulatory burden align with the estimates? If not, where did they differ?
- Was there a perceived change in consumer confidence in support provided by healthcare practitioners for smoking cessation?
- How many tests of e-cigarettes for nicotine content did the TGA carry out? What were the overall results of these?
- What evidence is there of ABF interception of imports of nicotine containing e-cigarettes?

**Table 5: Estimated timeframe**

Activity	Estimated date
Delegate's decision	21 December 2020
Drafting of amendment to the Poisons Standard	21 December 2020
Publication of consolidated Poisons Standard	February 2021
Amendment comes in to effect	1 October 2021
Enhanced post market testing of e-cigarettes for presence of nicotine- regulatory action taken as required	From effective date amendment comes into effect - ongoing
Education campaign	Mid first half of 2021 - ongoing
Evaluation	To commence approximately one year after amendment is given effect, after 1 October 2022

## Annexure A – Detailed analysis of Options 1, 2 and 3

### Option 1

311. A detailed analysis of the impacts on various stakeholders from maintaining the status quo is provided in table 6 below.

**Table 6: Impacts of maintaining the status quo – the inconsistency between regulation of imports and domestic sales by demographic**

IMPACTS OF MAINTAINING THE STATUS QUO	
<b>Youth</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• Availability of nicotine containing e-cigarettes by importation               <ul style="list-style-type: none"> <li>◦ As sales by domestic retailers are unlawful it is inappropriate to note the potential for domestic purchases as a benefit.</li> </ul> </li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• There is an increased potential for uptake of smoking in young adults who would otherwise be at low risk of initiating addiction to nicotine and to combustible cigarettes.</li> <li>• An increased addiction to nicotine and uptake of combustible cigarettes would have the effect of increasing, from the present rate of the total disease burden (in disability-adjusted life years (DALYs)) attributable to combustible tobacco use of 9.3%.<sup>126</sup> There could, therefore, be an increase in the present burden on tangible health care costs (\$6.8 billion), workplace costs (\$5 billion), costs related to premature deaths (\$1.8 billion) and other costs primarily associated with fires, litter and expenditure on tobacco by dependent smokers (\$5.7 billion). In addition to the tangible costs of smoking, there could be a further increase in intangible costs (e.g. the value of life lost, pain and suffering), both from premature mortality (\$92.1 billion) and from the lost quality of life of those experiencing smoking attributable ill-health (\$25.6 billion).<sup>24</sup></li> <li>• Users are exposed to chemicals and possible injury from malfunctioning e-cigarette.</li> <li>• There remains a risk of conviction for a criminal offence or civil penalty contravention because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used.</li> </ul>

<sup>126</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

<b>IMPACTS OF MAINTAINING THE STATUS QUO</b>	
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• Whilst nicotine containing e-cigarettes remain available to youth none of the public health risks associated with their use by this cohort is addressed – particularly noting the vulnerability of the adolescent brain to the rewarding effects of nicotine which, among other things, motivated the US Surgeon General to declare that youth use of any tobacco products including e-cigarettes is unsafe.</li> <li>• The status quo is a complete failure to heed the evidence that e-cigarettes are a gateway to smoking. It eschews the precautionary principle in not addressing the public health risks to youth.</li> <li>• Therefore, the risk to the health of today’s youth is too great to prefer the status quo.</li> </ul>
<b>All smokers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• Nicotine containing e-cigarettes may continue to be imported without additional effort.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The ease with which nicotine containing e-cigarettes remain available for purchase perpetuates the disincentive for a smoker to use NRT or to seek a medical practitioner’s assistance to stop smoking with the risk of less success in ceasing to smoke.</li> <li>• Smokers are liable to continue dual use – of combustible cigarettes and of nicotine containing e-cigarettes with the relevant health risk as noted above.</li> <li>• Increased addiction to nicotine and uptake of combustible cigarettes would have the effect of increasing, from the present rate of the total disease burden (in DALYs) attributable to combustible tobacco use of 9.3%<sup>127</sup> (see further the comments under Youth). The regressive impacts (on society’s more vulnerable) are also arguably perpetuated.</li> <li>• The risk of exposure to chemicals and possible injury from malfunctioning e-cigarette remain.</li> <li>• There is a risk that the use of nicotine containing e-cigarettes becomes a long-term substitute for smoking rather than a cessation tool with attenuated known and unknown risks to health of long-term use.</li> <li>• There is a continued risk of criminal offence or civil penalty because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• Whilst it is true that the status quo has the effect that those wishing to use e-cigarettes as an aid to smoking cessation are free of barriers to do so, there is no incentive to seek the support of a medical practitioner, likely the most successful approach to securing the desired outcome. Less harmful alternatives, including NRT, are likely not adequately canvassed. The other harmful effects – including of dual use, exposure to chemicals and the unknown impacts of long-term use remain. Users also remain at clear risk of committing a criminal offence or civil penalty contravention under state and territory law.</li> <li>• Therefore the benefit to smokers of the status quo is, at best, marginal.</li> </ul>
<b>Former smokers</b>	

<sup>127</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

<b>IMPACTS OF MAINTAINING THE STATUS QUO</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• Nicotine containing e-cigarettes remain available to be imported.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• As for smokers wanting to stop smoking.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• As for smokers wanting to stop smoking.</li> </ul>
<b>Children</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• N/A.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The risk of nicotine poisoning is maintained.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• By failing to address the risk of accidental nicotine poisoning by children, which may result in death, the status quo poses an unpalatable risk to this vulnerable population.</li> </ul>
<b>Retailers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• Nicotine containing e-cigarettes remain available to be imported for subsequent unlawful domestic sale.</li> <li>• Retailers will likely be able to maintain revenue from illegal sales.</li> <li>• Retailers will continue to maintain market share of sales of devices.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The ease with which nicotine containing e-cigarettes may be imported and the mark up thereon maintains the incentive for unlawful domestic supply.</li> <li>• The behaviour described in the previous dot point exposes a retailer to conviction for a criminal offence or contravention of civil penalty provision.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• Whilst true that retailers may continue to sell unlawfully nicotine containing e-cigarettes, preference of a regulatory outcome favouring unlawful behaviour, which fails to give weight to the desired public health outcome, is a flawed benefit-cost analysis.</li> </ul>
<b>Wholesalers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• The supply chain to domestic retailers remains open.</li> <li>• Wholesalers will likely be able to maintain revenue.</li> <li>• Wholesalers will likely maintain market share of sales of devices.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The ease with which nicotine containing e-cigarettes may be imported and the mark up thereon maintains the incentive for supply to retailers for unlawful retail supply.</li> <li>• The behaviour described in the previous dot point exposes a retailer to conviction for a criminal offence.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• As for retailers.</li> </ul>
<b>Medical practitioners</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden and therefore no change to regulatory burden.</li> </ul>

<b>IMPACTS OF MAINTAINING THE STATUS QUO</b>	
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• Medical practitioners have a reduced role in supporting smokers to be effective in their bid to stop smoking.</li> <li>• There is no or limited role for medical practitioners in arresting the uptake in nicotine containing e-cigarettes by 'youth'.</li> <li>• Medical practitioners are unlikely to advise on appropriate storage of nicotine containing e-cigarettes to reduce the risk of nicotine poisoning of children.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• Placing less weight on the absence of regulatory impact on medical practitioners than the weight on the role, which they may play in supporting patients' health / public health outcomes, gives too little importance to the outcomes, which may be achieved – for smokers in stopping smoking and for the public purse in reduced adverse public health outcomes. (as to which see the comments under youth and smokers and former smokers).</li> <li>• On this basis, that there is a benefit to medical practitioners of the status quo is questionable.</li> </ul>
<b>Pharmacists</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• Pharmacists have a reduced role in supporting smokers to be effective in their bid to stop smoking.</li> <li>• There is no or limited role for pharmacists in arresting the uptake in nicotine containing e-cigarettes by 'youth'.</li> <li>• Pharmacists are unlikely to advise on appropriate storage of nicotine containing e-cigarettes to reduce the risk of nicotine poisoning of children</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• As for medical practitioners.</li> </ul>
<b>Department</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no requirement to expend public money.</li> <li>• There is no regulatory burden on GPs, pharmacists, users of e-cigarettes, youth etc.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• There is a real risk that there will be an increase in the use of nicotine containing e-cigarettes by adolescents and young adults.</li> <li>• There is a real risk that patients who want to stop smoking have no external motivation or incentive to seek efficacious support.</li> <li>• The likelihood of child poisoning by accidental consumption of nicotine remains.</li> </ul>

## Option 2

312. A detailed analysis of the impacts on various stakeholders from public awareness campaign is provided in table 7 below.

**Table 7: Impacts of option 2 - Campaign - stop initiation / dependence on nicotine containing e-cigarette as well as smoking cessation**

IMPACTS OF A CAMPAIGN – STOP INITIATION / DEPENDENCE ON NICOTINE / SMOKING	
Youth	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is no additional regulatory burden.</li> <li>• Based on evidence of success of prior campaigns targeted at encouraging cessation of smoking but also noting the present use of e-cigarettes by US high school students after the relevant campaign, an appropriately targeted campaign is likely to have some success in arresting the use by adolescents and young adults of nicotine containing e-cigarettes.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The temptation of ease of import of nicotine containing e-cigarettes would remain. The temptation is likely to be especially strong for adolescents and young adults for whom the popularity of e-cigarettes is a function, not only of their addictive capacity and pharmacokinetic effect, but also of their perceived enhancement to image, ease of concealment and availability in a variety of flavours.</li> <li>• There is a continued risk of criminal offence or civil penalty because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• The public education awareness campaign is likely to have some success in arresting youth uptake of nicotine containing e-cigarettes.</li> <li>• However, the temptation of ease of import remains.</li> <li>• Therefore, this benefit is unlikely to be sufficient to adequately address the disadvantages of the option 1 (the status quo) because: <ul style="list-style-type: none"> <li>○ There remains an increased potential for uptake of smoking in young adults who would otherwise be at low risk of initiating use, and therefore addiction to, nicotine and combustible cigarettes.</li> <li>○ Increased addiction to nicotine and uptake of combustible cigarettes would have the effect of increasing, from the present rate of the total disease burden (in DALYs) attributable to combustible tobacco use of 9.3%.<sup>128</sup> This would mean that Australians would not only continue to suffer from co-morbidities (such as cardiovascular disease and diabetes) associated with smoking, there is a very real risk of these incidences increasing.</li> <li>○ In turn, there would be an increased burden on the public health system to supply the necessary medications, supports and hospitalisations.</li> <li>○ Users are also exposed to chemicals and possible injury from malfunctioning e-cigarettes.</li> </ul> </li> </ul>

<sup>128</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

<b>IMPACTS OF A CAMPAIGN – STOP INITIATION / DEPENDENCE ON NICOTINE / SMOKING</b>	
	<ul style="list-style-type: none"> <li>○ On top of the financial burden of addiction, there is the unquantifiable cost to society of premature deaths</li> <li>● Further, the risk of criminal offence or civil penalty because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used is maintained.</li> </ul>
<b>Smokers wanting to stop</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>● There is no additional regulatory burden.</li> <li>● Based on evidence of success of prior campaigns targeted at encouraging cessation of smoking an appropriately targeted campaign is likely to have some success in encouraging smokers to attempt to quit smoking and for the effort to be sustained.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>● Evidence demonstrates that a campaign alone will not effect durable results; ‘nicotine addiction is a chronic, relapsing disorder that benefits from long-term management and intensive treatment approaches’<sup>129</sup>. More intensive and longer behavioural and pharmacological interventions together is the optimal treatment based on ‘overwhelming scientific evidence’.</li> <li>● The present 9.3% of the total disease burden (in DALYs) attributable to combustible tobacco use <i>may</i> be maintained or at least not materially reduced.<sup>130</sup> In turn, there is a real risk that the overall social costs of tobacco use in Australia may plateau.</li> <li>● There is a continued risk of criminal offence or civil penalty because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>● The public education awareness campaign is most likely to be somewhat successful in encouraging smokers to stop smoking.</li> <li>● However, smokers are not guaranteed to receive the support that the nature of nicotine addiction requires to get the best outcome for a person who wants to stop smoking (as advised by the US General).</li> <li>● Therefore, the benefit is unlikely to be sufficient to adequately address the disadvantages of option 1 (the status quo) because: <ul style="list-style-type: none"> <li>○ the present 9.3% of the total disease burden (in DALYs) attributable to combustible tobacco use <i>may</i> be maintained or at least not materially reduced <sup>131</sup> This would mean that Australians would continue to suffer from co-morbidities (such as cardiovascular disease and diabetes) associated with smoking. In turn, the burden on the public health system to supply the necessary medications, supports and hospitalisations would be maintained. Society would continue to experience unnecessary human grief from premature deaths.</li> <li>○ Users are also exposed to chemicals and possible injury from malfunctioning e-cigarette.</li> </ul> </li> </ul>

<sup>129</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>130</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

<sup>131</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

<b>IMPACTS OF A CAMPAIGN – STOP INITIATION / DEPENDENCE ON NICOTINE / SMOKING</b>	
	<ul style="list-style-type: none"> <li>Further the risk of criminal offence or civil penalty because of the legal uncertainty as to whether e-cigarettes containing nicotine may be lawfully possessed / used is maintained.</li> </ul>
<b>Former smokers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is no additional regulatory burden.</li> <li>The resolve of former smokers to no longer smoke may be reinforced.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>There is no anticipated disadvantage for former smokers of the campaign.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>There is no obvious net benefit or net disadvantage from the public awareness campaign for former smokers.</li> </ul>
<b>Children</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>The public awareness campaign may assist with educating e-cigarette users about appropriate storage of e-liquid refills.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>In the absence of child resistant closures being mandated, the risk of nicotine poisoning of children persists.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>The failure of a public awareness campaign to include a mandate for child resistant closures for e-liquid refills means that the risk of accidental nicotine poisoning by children, which may result in death, persists. There is a marginal benefit of the public awareness campaign for this vulnerable population.</li> </ul>
<b>Retailers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is no additional regulatory burden.</li> <li>Nicotine containing e-cigarettes remain available for importation for unlawful domestic sale.</li> <li>Retailers are, largely, likely to maintain revenue from illegal sales.</li> <li>Retailers' market share in sales of devices is likely to be maintained.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>The ease with which nicotine containing e-cigarettes may be imported and the mark up thereon maintains the incentive for unlawful domestic supply.</li> <li>The behaviour described in the previous dot point exposes a retailer to conviction of a criminal offence.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>Whilst true that retailers may continue to sell unlawfully nicotine containing e-cigarettes, preference of a regulatory outcome favouring unlawful behaviour is flawed and should therefore be discounted.</li> </ul>
<b>Wholesalers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is no additional regulatory burden.</li> <li>The wholesale supply chain to domestic retailers remains open.</li> <li>Wholesalers' revenue from illegal sales is likely to be maintained.</li> <li>Wholesalers' market share in sales of devices is likely to be maintained.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>The ease with which nicotine containing e-cigarettes may be imported and the mark up thereon maintains the incentive for unlawful domestic supply.</li> <li>The behaviour described in the previous dot point exposes a retailer to conviction for a criminal offence.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>As for retailers.</li> </ul>



<b>IMPACTS OF A CAMPAIGN – STOP INITIATION / DEPENDENCE ON NICOTINE / SMOKING</b>	
<b>Medical practitioners</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is no additional regulatory burden.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>Medical practitioners have a little or no role in supporting smokers to be effective in their bid to stop smoking.</li> <li>There is no or limited role for medical practitioners in arresting the uptake in nicotine containing e-cigarettes by 'youth'.</li> <li>Because medical practitioners are not necessarily directly involved in their patient's choice of nicotine supply measure there is limited opportunity to advise on the appropriate storage of nicotine containing e-cigarettes. There is, therefore, a risk that this will not happen.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>Because the public awareness campaign relies on moral suasion to encourage smokers to stop smoking, there is a risk that medical practitioners may not play the central role a successful smoking cessation policy would require. Coupled with the absence of any role in arresting uptake in adolescent and young adults and in supporting storage of e-liquid refills away from children, the effect is to cut at the heart of a medical practitioner's function – to support patients' health / public health outcomes.</li> <li>On this basis, there is a marginal benefit to medical practitioners of the public awareness campaign.</li> </ul>
<b>Pharmacists</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is no additional regulatory burden.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>Pharmacists have a little or no role in supporting smokers to be effective in their bid to stop smoking.</li> <li>There is no or limited role for pharmacists in arresting the uptake in nicotine containing e-cigarettes by 'youth'.</li> <li>Pharmacists are unlikely to advise on appropriate storage of nicotine containing e-cigarettes to reduce the risk of nicotine poisoning of children.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>As for medical practitioners.</li> </ul>
<b>Department</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is potential to arrest the increase in use of nicotine containing e-cigarettes by adolescents and young adults.</li> <li>There is a potential to encourage patients who want to stop smoking to seek efficacious support, not already widely used (such as the Quit program).</li> <li>The likelihood of child poisoning by accidental consumption of nicotine remains.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>There is a requirement to expend public money on a public awareness campaign.</li> <li>Although likely to make some inroads, the confidence of achieving the specified regulatory objectives is muted because the regulatory lacuna exploited by e-cigarette users and ever users remains importation of nicotine containing e-cigarettes.</li> </ul>

## Option 3

313. A detailed analysis of the impacts on various stakeholders from including nicotine for all human use in Schedule 4 of the Poisons Standard and mandating child resistant closures is provided in table 8 below.

**Table 8: Impacts of Option 3- Include nicotine for *all* human use in Schedule 4 of the Poisons Standard with requirement for containers to use child resistant closures**

IMPACTS IF NICOTINE FOR <i>ALL</i> HUMAN USE IS A SCHEDULE 4 MEDICINE; CHILD RESISTANT CLOSURES MANDATED	
Youth	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• The clear benefit to youth ever users of Option 3 would arise because there would be no <i>lawful</i> means to secure a supply of e-cigarettes:               <ul style="list-style-type: none"> <li>○ Because importation of nicotine containing e-cigarettes by adolescents and young adults is restricted unless with a prescription there is no lawful means by which this stakeholder group may access nicotine containing e-cigarettes (noting that a prescription for smoking cessation is not appropriate for an ever user because that is not appropriately ‘medical use’).                   <ul style="list-style-type: none"> <li>§ It is noted that, although the risk of commission of a criminal offence or civil penalty contravention is likely to be highly effective in deterring purchase by this cohort (that is, without a prescription), it may not be 100% effective. In particular, a person may, despite the risk of committing a criminal offence or civil penalty contravention, order nicotine containing e-cigarettes from an international retailer without a prescription. Particularly having regard to the fact that this the case under the personal importation scheme for any prescription medicine and that the individual risks conviction, little weight is given in the analysis to the risk of this unlawful behaviour.</li> </ul> </li> <li>○ The Australian Border Force (Customs), in accordance with the advice of the TGA, would have power to detain personally imported nicotine containing e-cigarettes, pending confirmation that the import is in accordance with a prescription.</li> <li>○ The Australian Border Force (Customs), in accordance with the advice of the TGA, would have power to detain commercially imported nicotine containing e-cigarettes, pending confirmation that the import is in accordance with an approval or authority from the TGA or in accordance with the ‘lock and key’ wholesale exemption.</li> </ul> </li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• There is a regulatory burden for youth of the effort required to understand what the scheduling change would mean, that nicotine containing e-cigarettes are available by prescription only. Noetic’s estimate for this burden is included in the disadvantages for smokers and former smokers (below).</li> </ul>
<b>Net Outcome</b>	<ul style="list-style-type: none"> <li>• The key benefit to this cohort of the scheduling reform would be to reduce (for ever users, remove) the potential for uptake of smoking in adolescents and young adults who would otherwise be at low risk of initiating addiction to</li> </ul>

**IMPACTS IF NICOTINE FOR ALL HUMAN USE IS A SCHEDULE 4 MEDICINE; CHILD RESISTANT CLOSURES MANDATED**

	<p>nicotine and to smoking.</p> <ul style="list-style-type: none"> <li>• As earlier noted, the risk of commission of a criminal offence or civil penalty contravention is likely to be highly effective in deterring purchase by this cohort (that is, without a prescription), though possibly not 100% effective. Further, the risk of unlawful behaviour is appropriately not considered.</li> <li>• This option would therefore largely deliver on one of the key objectives of the regulatory action. There is little associated regulatory burden.</li> <li>• Accordingly, there is a clear benefit to youth from including nicotine for all human use as a prescription only medicine.</li> </ul>
<b>Smokers and former smokers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• Smokers and former-smokers would receive the benefit of robust support to stop smoking because the scheduling reform necessarily includes the support of a medical practitioner and therefore: <ul style="list-style-type: none"> <li>○ there is a greater likelihood of quitting;</li> <li>○ if the patient is given a prescription for nicotine containing e-cigarettes there is greater likelihood that using a quality product with reduced risk of injury;</li> <li>○ the risk of long term health complications from use of e-cigarettes is subject to medical supervision; and</li> <li>○ there is a greater chance of stopping smoking.</li> </ul> </li> <li>• Reduced smoking rates would have a significant impact. The present burden of tobacco use - best captured with the leading statistic that it remains a leading cause of preventable death and disability in Australia and was estimated to kill almost 21,000 Australians in 2015<sup>132</sup> - would be reduced.</li> <li>• Specifically, there would be a reduction on the most recent available estimates of the overall social (including health) costs of tobacco use in Australia – at \$137 billion in 2015-16. This included \$19.2 billion in tangible costs and \$177.7 billion in intangible costs.<sup>133</sup></li> <li>• Tangible costs included health care costs (\$6.8 billion), workplace costs (\$5 billion), costs related to premature deaths (\$1.8 billion) and other costs primarily associated with fires, litter and expenditure on tobacco by dependent smokers (\$5.7 billion). In addition to the tangible costs of smoking, there are substantial intangible costs (e.g. the value of life lost, pain and suffering), both from premature mortality (\$92.1 billion) and from the lost quality of life of those experiencing smoking attributable ill health (\$25.6 billion).<sup>134</sup></li> <li>• The present 9.3% of the total disease burden (in DALYs) attributable to combustible tobacco use would likely decrease with associated reduction in</li> </ul>

<sup>132</sup> Australian Institute of Health and Welfare, Burden of tobacco use in Australia: Australian Burden of Disease Study 2015. Australian Burden of Disease series no. 21. Cat. no. BOD 20. Canberra: AIHW;2019 Available from: <https://www.aihw.gov.au/getmedia/953dcb20-b369-4c6b-b20f-526bdead14cb/aihw-bod-20.pdf.aspx?inline=true>.

<sup>133</sup> Tait R, Whetton S and Alsop S. Identifying the social costs of tobacco use in Australia in 2015/16. Perth: National Drug Research Institute, Curtin University; October 2019. Available from: <https://ndri.curtin.edu.au/ndri/media/documents/publications/T273.pdf>.

<sup>134</sup> Ibid

**IMPACTS IF NICOTINE FOR ALL HUMAN USE IS A SCHEDULE 4 MEDICINE; CHILD RESISTANT CLOSURES MANDATED**

	<p>cost to the health care system.<sup>135</sup></p> <ul style="list-style-type: none"> <li>• Nevertheless, there may be some who may not be attracted to the opportunity: <ul style="list-style-type: none"> <li>○ the inclusion of the requirement for a prescription before a person may get access to nicotine containing e-cigarettes may be seen as creating unnecessary barriers to access. In turn, this is likely, at least to some degree, to undermine any chance smokers will have to stop smoking with the appropriate support.</li> <li>○ To the extent that this is borne out, the effect would be that people will continue to die from tobacco related disease and there would be other associated costs. Smokers would be even more marginalised.</li> <li>○ The possibility of individuals being committed to the libertarian principle of the right to individual choice including for decisions that will negatively affect their own personal health as well as the public health system to choose not to try to stop smoking is given no weight. This is because there is widespread evidence that almost all smokers want to stop.</li> </ul> </li> <li>• Further, it is reasonable to assume a differential impact among smokers because of socio-economic circumstances including of Aboriginal and Torres Strait Islander peoples. In particular: <ul style="list-style-type: none"> <li>○ Australians who are smokers and who are experiencing mental illness or other form of disadvantage (for example, they experience homelessness or are in prison) do not actively engage in the health system to prioritise their health. People in this cohort, in particular, are likely to find it difficult to navigate the process to access nicotine containing e-cigarettes. This would be particularly acute in remote locations where even a tele-health appointment with a GP is not guaranteed.</li> </ul> </li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• The disadvantage to smokers (and former smokers) is the effort required to access nicotine containing e-cigarettes, assessed by Noetic as follows.</li> <li>• Noetic has assumed that the e-cigarette users most likely to be impacted from an awareness perspective are those who use e-cigarettes at least monthly calculated by reference to the July 2020 AIHW published National Drug Strategy Household Survey. With much of the awareness material already available and use of various media options, Noetic has estimated this to take 2 minutes per nicotine e-cigarette user.</li> <li>• On the basis of the effort required to source nicotine containing e-cigarettes, Noetic has assumed that there will be an initial drop off in the population wishing to continue to use the product – by those reporting in the July 2020 AIHW survey as using e-cigarettes ‘less than monthly’ and ‘at least monthly’, that is 35% of the current use population. For the remaining 65%, Noetic has</li> </ul>

<sup>135</sup> Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. Canberra: AIHW, 2019

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estimated the frequency of visits to a medical practitioner per year by reference to the age bracket of patients as reported in the ABS Patient Experience dataset and where that frequency exceeds two visits per year to assume no extra visits are required for GP assistance with stopping smoking. Noetic has also assumed, over the course of the 10-year regulatory period, e-cigarette users will decrease both because of cessation attempts and increased consumer awareness of the health risks of use, thereby applying a 10% reduction per year.

- For the balance of the population the additional regulatory burden for this population is the effort required to:
  - search for a medical practitioner willing to prescribe nicotine containing e-cigarettes
  - make an initial and subsequent appointments for a consultation with their GP
  - attend the consultation with their GP either in person or virtually
    - § On the basis of the recent uptake in virtual consultations and responses to Accenture's 2019 Digital Health Consumer Survey in which 45% of respondents indicated a preference for a medical provider if they communicated by video and 74% indicated a preference for those providing electronic prescriptions, Noetic has estimated 20% of initial GP visits will be virtual with an annual growth rate of 10%.
  - if attending the consultation in person, travel to their GP, which Noetic has estimated, is a total of 30 minutes with an average wait time at the surgery of 30 minutes. Noetic estimates the average consultation time is to be 15 minutes. An additional 5 minutes was allocated for consultations for which the conversation around smoking cessation was 'added' to an existing consult (initial consult only).
  - The GP is assumed by Noetic to prescribe his or her patient nicotine containing e-cigarettes in 85% of consultations – alternative smoking cessation measures being considered appropriate for the remaining 15 %.
  - If the GP prescribes nicotine containing e-cigarettes (assumed by Noetic to be valid for 12 months and reflecting a range of risk attitudes from the GP to allow for 5 repeats) users will fill the prescription either:
    - § at the community pharmacy, which is assumed by Noetic:
      - to hold the AP approval and to engage with the wholesaler to secure supply
      - consistently with the Pharmacy Board of Australia's *Guidelines for Dispensing Medicines*, to be monthly – involving travel time calculated by proximate location to the GP surgery or, online, ordering time, which may include uploading a prescription and is assumed to increase in popularity over the 10-year period.
      - Noetic has assumed domestic online ordering is increasingly popular over the 10-year regulatory period because of reduced postage costs, absence of international transaction fees and increased comfort with domestic retailers (30% of users).
      - Noetic has also assumed that 20% of users (12 times per year) will make an in person visit to pharmacies reflecting the traditional means of filling a prescription.

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	<p>Because of co-morbidities associated with smokers, and based on data from the National Drug Research Institute, Curtin University has assumed 30% of these physical visits are not exclusive.</p> <p>§ with an international retailer, estimated by Noetic to be the most popular option (50% of users), – involving ordering time with no additional regulatory burden because this is the means presently used to source a prescription.</p> <ul style="list-style-type: none"> <li>○ If the package containing the e-cigarette nicotine is detected at the border by the ABF then to avoid prosecution or civil penalty contravention and to justify return of the goods, the importer must provide the a valid prescription/doctor’s letter. <ul style="list-style-type: none"> <li>§ Although the risk of commission of a criminal offence or civil penalty contravention is likely to be highly effective in ensuring, in the case for smokers and former smokers, purchase with a prescription, it may not be 100% effective. In particular, a person may, despite the risk of committing a criminal offence or civil penalty contravention, order nicotine containing e-cigarettes from an international retailer without a prescription, chancing detection by the ABF. Particularly, having regard to the fact that this the case under the personal importation scheme for any prescription medicine and that the individual risks conviction, little weight is given to the risk of unlawful behaviour.</li> </ul> </li> <li>○ Further, Noetic has advised that it is unable to determine the likely detection rate at the border for e-cigarettes legally imported to Australia under the personal importation scheme. However, given that all is required for release of the goods is advice from the TGA to the ABF that the good can be released or the provision of contact information and a short statement pertaining to the holding of a valid prescription (and likely a copy of the prescription) on the ‘Claim for return of seized goods’ (Form B144) – which Noetic assesses should take no more than five minutes to complete and return to the ABF – Noetic does not consider any arising regulatory burden likely to be material to the overall regulatory costing.</li> </ul> <p>Taking all these inputs into account Noetic estimates the regulatory burden for smokers to be \$48,719,284. In annual terms, the average annual regulatory burden over the 10-year regulatory period is \$4.9m.</p> <p>There are also a number of alleged behavioural imposts which are canvassed at paragraph 254 to paragraph 260.</p>
<p><b>Net outcome</b></p>	<ul style="list-style-type: none"> <li>• On the one hand, there is the cost to smokers and former smokers from the proposed scheduling reform arising because of the additional required consultations with medical practitioners and the effort required to fill a prescription on a monthly basis, along with possible requirement to evidence lawful importation with production of a copy of a prescription. <ul style="list-style-type: none"> <li>○ Noetic has estimated the total regulatory burden for smokers of the scheduling clarification is \$48,719,284. In annual terms, the average annual regulatory burden over the 10-year regulatory period is \$4.9m.</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>• On the other hand, even accounting for those who may find the increased barriers to access to smoking cessation measures insurmountable (for example those who are experiencing mental illness or other form of disadvantage (for example, they experience homelessness or are in prison), overall there is an anticipated 'health' improvement. This would be to the personal health of a person who succeeds in stopping smoking as well as improvement in public health outcomes. The October 2019 Curtin University estimates of the overall (including health) costs of tobacco use in Australia of \$137 billion in 2015-16 are projected to fall. Precisely by what amount will be difficult to say.</li> <li>• The outcome anticipated in the previous dot point – more smokers giving up smoking - is more likely under Option 3 because of the support a medical practitioner will give to the smoker. See, for example, advice from the US Surgeon General that the 'current paradigm for smoking cessation conceptualises nicotine addiction as a chronic, relapsing disorder that benefits from long-term management and intensive treatment approaches.'<sup>136</sup> Accordingly, even noting the risk of some smokers not engaging with a medical practitioner, Option 3 is likely to deliver on the regulatory objectives most effectively.</li> <li>• Having regard to the statistics on the present cost of smoking to Australians and to Australian society more generally, the potential for improved health outcomes and reduced health care costs is significant. The burden of grief to loved ones from serious illness of their loved and / or early death will also necessarily not need to be endured by as many.</li> <li>• Accordingly, there is an overall net benefit anticipated for smokers and former smokers from the scheduling change.</li> </ul>
<b>Children</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• A child resistant closure requirement in the scheduling decision, combined with advice from medical practitioners about appropriate storage of a medicine, means that the risk of accidental poisoning to children would be more or less eliminated.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• There is no disadvantage.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• There is a clear benefit to children of a scheduling decision, with no accompanying disadvantage to this vulnerable population.</li> </ul>
<b>Retailers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• Retailers maintain their ability to supply non-nicotine containing e-cigarettes and flavours to mix with nicotine supplied on prescription by a pharmacy.</li> </ul>

<sup>136</sup> US Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. Rockville: Public Health Service, Office of the Surgeon General; Atlanta: Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Available from: <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

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	<ul style="list-style-type: none"> <li>Retailers are also likely to maintain their share in the device market (on the basis that pharmacies, as represented by the Pharmacy Guild, have advised there is no interest in the supply of a device alone).</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>Because it is presently unlawful to sell nicotine containing e-cigarettes, the impact of the scheduling decision on sales of these goods is zero.</li> <li>Further, it is questionable that any impact on an unlawful activity is appropriately included as part of a regulatory burden.</li> <li>To the extent that it is appropriate, the impact, which because of its unlawful nature cannot be estimated, is: <ul style="list-style-type: none"> <li>The availability of nicotine containing e-cigarettes for importation for unlawful domestic sale is significantly affected and likely removed.</li> <li>Lost revenue from not being able to make illegal sales.</li> <li>No impact on market share in sales of devices.</li> </ul> </li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>With the sale of nicotine containing e-cigarettes presently unlawful, and pharmacists not entering the market for accessories including flavours, the position of retailers is not affected.</li> </ul>
<b>Wholesalers</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>Wholesalers have an opportunity to enter a new market.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>There is a regulatory burden for wholesalers of the effort required to understand what the scheduling change would mean, that nicotine containing e-cigarettes are available by prescription only.</li> <li>Noetic estimates that future importers / wholesalers of e-cigarettes containing nicotine will likely already be involved with importation of pharmaceuticals. There is, therefore, no further material regulatory burden</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>There is a good opportunity for wholesalers to enter a new market with no additional regulatory burden.</li> </ul>
<b>Medical practitioners</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>There is an increased opportunity to influence positively smoker patients to stop smoking – in accordance with the RACGP guidelines and to monitor their own going health. <ul style="list-style-type: none"> <li>Whether the opportunity to support a patient to stop smoking involves a prescription for nicotine containing e-cigarettes or another form of treatment is irrelevant. The benefit recorded here is the additional incentive created for medical practitioners by their patients, themselves incentivised by Option 3, to see their medical practitioner to seek assistance to stop smoking.</li> </ul> </li> <li>There is an increased opportunity to support the reduced risk of nicotine poisoning by children by advice to patients on appropriate storage practices.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>The disadvantage to this cohort is the effort required to be able to access lawfully nicotine containing e-cigarettes for their patients, assessed by Noetic as follows.</li> <li>Medical practitioners are required: <ul style="list-style-type: none"> <li>to understand what the scheduling change would mean that nicotine containing e-cigarettes are available by prescription only. <ul style="list-style-type: none"> <li>§ They will need to understand more about the product, its reliability and the reliability of sources, to know the effective</li> </ul> </li> </ul> </li> </ul>



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absorption from different devices and education on how to taper off those products. Medical practitioners may be concerned about the role that they will assume, when there is no nicotine containing e-cigarette entered on the ARTG, as 'gatekeeper'.

- when there are no e-cigarettes containing nicotine entered on the ARTG, to understand how to become an Authorised Prescriber or to make a SAS B application.
- When there are no e-cigarettes containing nicotine entered on the ARTG the medical practitioner's effort to support a patient to stop smoking using e-cigarettes would be as follows. It is important to note that, as The 3 possible lawful means by which a patient might lawfully fill a prescription from their medical practitioner affects the regulatory impost on the medical practitioner of the scheduling decision. The personal importation scheme would not require the medical practitioner either to be an Authorised Prescriber or to apply for SAS B approval. Noetic's estimate of regulatory burden accounts for the consequential impact of these two access pathways on the effort required by the medical practitioner to secure lawful access to nicotine containing e-cigarettes for their patient.

**Authorised Prescriber**

- Making an application to become an authorised prescriber including, if necessary, by establishing an account with the TGA. Noetic has assumed that the necessity for AP authorisation is extant for the first year of the scheduling change and, on the basis of potential GP reluctance to prescribe nicotine containing e-cigarettes and patient preference for supply by international retailers, 50% of clinics would seek AP authorisation. Noetic assumes 20% of these GPs would require familiarising themselves with AP requirements.
- Preparing and submitting twice yearly reports to the TGA detailing new and repeat patients

OR

**SAS B**

- If necessary, establishing an account with the TGA. Noetic has assumed that the necessity for SAS B approval is extant for the first year of the scheduling change.
- Applying for SAS B approval per patient. Reflecting the comparative ease of prescribing with the AP authorisation and the preference for international access, Noetic has assumed that only 5% of consultations would require SAS B approval

Future population considerations assume that a nicotine containing e-cigarette will be entered on the ARTG within a year or so of the scheduling decision. Further, not all access to e-cigarettes would require a GP to have either AP authorisation or SAS B approval from the TGA. Accordingly, it is likely that over the 10-year regulatory period the effort to secure AP authorisation or SAS B approval will reduce. Consultation requirements will be maintained but, assuming the success of the support provided to smokers to stop smoking, the demand for 'smoking cessation' consultations will also fall.

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	<p>Taking all these inputs into account Noetic estimates the regulatory burden for APs to be \$244,292 and for SAS B \$534,327, a total of \$778,619.</p> <p>Any perception by medical practitioners of a barrier created by the requirements associated with prescribing nicotine containing e-cigarettes has been, more or less, discounted because of the marginal nature of this impost. Additionally, the Department is committed to education / assistance / development of clinical guidelines to support the practical delivery of Option 3. In this regard, the Department defers to the expertise of medical practitioners. The Department appreciates they are skilled practitioners; use of unapproved medicines is not an unknown. Access is also not necessarily the outcome of consultation with a patient. The benefit will be that both the user and the health practitioner will know what the user is ingesting and that users might overcome their nicotine addiction</p>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• The Noetic assessed regulatory burden for medical practitioners including the initial effort for medical practitioners to become aware of the implications of the scheduling reform decision and to consider making an application to be an AP with the six monthly reporting and the SAS B obligations as \$962,807. This is relatively marginal.</li> <li>• On the other hand, the benefit to medical practitioners is clear – the increased opportunity for medical practitioners to support better health outcomes for their patients who are smokers and for the public health system more generally, which goes to the heart of what a medical practitioner is trained to do.</li> <li>• On this basis, Option 3 is attractive for its opportunity for medical practice.</li> </ul>
<b>Pharmacists</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• Pharmacists have an opportunity to enter a new market.</li> <li>• Pharmacists have an opportunity to influence positively smoker patients to stop smoking whether by NRT or other including nicotine containing e-cigarettes.</li> <li>• If e-cigarettes are prescribed, the pharmacist is well placed to monitor the health effects on the patient.</li> <li>• Pharmacists have an opportunity to support the reduced risk of nicotine poisoning by children.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• As new therapeutic goods constantly become available in Australia, the process for pharmacists of becoming aware of the variation in the treatment of nicotine containing e-cigarettes is a business as usual activity. Noetic has therefore excluded awareness activities for pharmacists from the regulatory impact of the proposed amendment of the scheduling of nicotine in the Poisons Standard.</li> </ul>
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>• With a new business opportunity grounded in an opportunity to support their patients to stop smoking, and no regulatory impost, pharmacists will benefit from the proposed scheduling decision. They will also be included in the discussions with the Department on necessary education / assistance / development of clinical guidelines to support the practical delivery of Option 3.</li> </ul>
<b>Applicant for inclusion of an e-cigarette containing nicotine in the ARTG</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>• There is a new business opportunity for a relevant business to supply a new therapeutic good.</li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>• See the Noetic costing based on TGA advised regulatory steps and estimates of products with two strengths and three flavours per sponsor's five product</li> </ul>

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	range resulting in six separate ARTG entries per sponsor.
<b>Net outcome</b>	<ul style="list-style-type: none"> <li>The opportunity to supply a new therapeutic good and the costs associated in relation to create that opportunity are business as usual activities for medical suppliers.</li> </ul>
<b>Department</b>	
<b>Benefit</b>	<ul style="list-style-type: none"> <li>The objectives of the regulatory response are likely delivered: <ul style="list-style-type: none"> <li>It would arrest of the increase in use of nicotine containing e-cigarettes by adolescents and young adults.</li> <li>Patients who want to stop smoking incentivised to seek efficacious support, not already widely used (such as the Quit program).</li> <li>If the Delegate decides to include a child resistant closure requirement the risk of poisoning, with the advice from medical practitioners about appropriate storage of a medicine, is more or less eliminated.</li> </ul> </li> </ul>
<b>Disadvantage</b>	<ul style="list-style-type: none"> <li>There are no disadvantages to the Department.</li> </ul>

## Annexure B – Regulation of nicotine – a shared Commonwealth and State responsibility

### Commonwealth regulation – Poisons Standard given effect by state and territory law

#### How the Poisons Standard works

314. The Poisons Standard is a legislative instrument for the purposes of the *Legislation Act 2003*. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons.
315. The Poisons Standard has been presented with a view to promoting uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia.
316. The Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
317. The Schedules are set out in table 9.

**Table 9: Schedules in the Poisons Standard**

<b>Schedule 1</b>	Not currently in use
<b>Schedule 2</b>	Pharmacy Medicine
<b>Schedule 3</b>	Pharmacist Only Medicine
<b>Schedule 4</b>	Prescription Only Medicine OR Prescription Animal Remedy
<b>Schedule 5</b>	Caution
<b>Schedule 6</b>	Poison
<b>Schedule 7</b>	Dangerous Poison
<b>Schedule 8</b>	Controlled Drug
<b>Schedule 9</b>	Prohibited Substance

**Schedule 10**

Substances of such danger to health as to warrant prohibition of sale, supply and use

318. The numbering of schedules 2, 3, 4 and 8 signifies an increasing level of professional healthcare intervention combined with increasingly stricter restrictions on availability.
319. Relevantly, appendices D, F and J are considered by reference to the following considerations.
320. Appendix D – Additional controls on possession or supply of poisons included in Schedules 4 or 8
- Inclusion of a substance in Appendix D may be considered by the Delegate for any human or veterinary medicine where the assessment of the proposal identifies:
    - i. a specific health risk that may be mitigated by restricting availability through specialist medical practitioners; or
    - ii. significant potential for illicit diversion and/or abuse which does not warrant inclusion in Schedule 8 but warrants particular control of possession; or
    - iii. a specific high potential for abuse, particular international treaty restrictions on availability or other matters of national public health policy which when weighed against the need for access to the substance, warrants, in addition to inclusion of the substance in Schedule 4 or 8, further restrictions on access, such as authorisation by the Delegate of the Department of Health or some other appropriate State/Territory or Commonwealth authority.
321. Appendix F – Warning statements and general safety directions for poisons
- First aid and safety directions for human medicines are assessed as a component of the registration requirements and are included in the [Required Advisory Statements for Medicines Labels](#). This requirement applies to medicines, which are exempted from the requirements of the TG Act such as medicines that are compounded by a pharmacist on a prescription for an individual patient.
  - These directions supplement the directions for use of the product by identifying specific hazards of the product, precautions to be taken, any personal protective equipment to be worn during use of the product and appropriate first aid measures to be taken following any misadventure involving the product. Entries are based on the assessment of the scheduling proposal and take into account current best practice in occupational and emergency medicine. The Delegate may make an entry in these Appendices as part of the scheduling decision for a new substance. An entry or amended entry may also be made in these appendices following a rescheduling application and consultation with the ACCS, ACMS or a Joint meeting. New or amended entries in these appendices may also be made following a specific application in relation to these Appendices, after consultation with ACCS, ACMS or a Joint meeting

## 322. Appendix J – Schedule 7 poisons requiring additional controls on availability and use

- A new or amended entry to Appendix J will only be considered if:
  - i. Significant, or potential to cause, severe and possible irreversible injury may occur without the individual being aware of exposure – whether that is a single or repeated exposure or a low or high dose exposure.
  - ii. Specialised skills and/or equipment are required to mitigate the risks of using the poison.
  - iii. The patterns of use of the poison pose an unacceptable risk resulting from direct or indirect exposure to the public. The Delegate may make a new entry or vary an existing entry following consultation with the ACCS and will consider the need for any additional State and Territory controls over access, training or possession of the substance, to ensure its safe use.

## 323. There are two schedules of, and two appendices to, the Poisons Standard, which are presently relevant to the regulation of nicotine. These are:

- **Schedule 4 (Prescription Only Medicine)**, which includes '*Substances the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription*';
- **Schedule 7 (Dangerous Poison)**, which includes '*Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply*'; and
- **Appendix F** which provides for '*warning statements and general safety directions for poisons*'.
- **Appendix J**, which provides a list '*of poisons included in Schedule 7 where additional specified conditions apply to their availability and use*'.

## 324. Scheduling decisions involve a risk-benefit consideration in the context of protecting public health. The risk-benefit consideration takes into account factors specified in s 52E(1) of the TG Act :

- the risks and benefits of the use of a substance;
- the purposes for which a substance is to be used and the extent of use of a substance;
- the toxicity of a substance;
- the dosage, formulation, labelling, packaging and presentation of a substance;
- the potential for abuse of a substance; and
- any other matters considered necessary to protect public health.

325. The [Scheduling Policy Framework \(SPF\)](#) provides that substances are scheduled according to the risk of harm and the level of access control required to protect consumers.
326. Nicotine is presently relevantly included in:
- Schedule 4 to the Poisons Standard, where it is '*in preparations for human **therapeutic** use*', except for '*use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use*' (i.e., in nicotine patches and chewing gum); or
  - Schedule 7 and Appendices F and J to the Poisons Standard, in preparations for human non-therapeutic use except in tobacco prepared and packed for smoking.

### Commonwealth regulation - nicotine for human therapeutic use – Therapeutic Goods Act

327. The importation and subsequent supply of nicotine for human therapeutic use as well as its advertisement is regulated under the TG Act and subordinate regulations. The TG Act establishes a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The TGA, part of the Australian Government Department of Health, is responsible for regulating therapeutic goods (relevantly including medicines) under the TG Act and relevant regulations to ensure those goods are of acceptable quality, safety and efficacy.
328. Subsection 3(1) of the TG Act relevantly provides that goods will only be therapeutic goods where they '*are represented in any way to be, or... are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be... for **therapeutic** use*'. Therapeutic use is defined as '*use in or in connection with*', among other things, '*preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in person*' or '*influencing, inhibiting or modifying a physiological process in persons*'.
329. Where nicotine is for therapeutic use (and is therefore a therapeutic good within the meaning of the TG Act), it must be entered on the ARTG to be lawfully supplied in, imported into, or exported from Australia, unless those goods are otherwise the subject of an exemption, approval or authority under the TG Act.<sup>137</sup>
330. There are two tiers of regulatory requirements that medicines must meet in order to be included in the ARTG, corresponding with the degree of risk based on a products ingredients, therapeutic indications (claimed health benefits) and presentation:
- Lower risk medicines are *listed* on the ARTG and are identified by an AUST L or AUSTL(A) number on their label. They are available for self-selection by consumers.

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<sup>137</sup> Section 19B and 19D of the TG Act.

- Higher risk medicines (for example, prescription medicines specified in Schedule 4 of the Poisons Standard) are *registered* on the ARTG. These are identified by an AUST R number on their label and may be accessed over-the-counter.

331. Some nicotine containing products, such as gums, sprays and inhalators, although containing unscheduled nicotine are registered on the ARTG.

### ***Lawful supply of nicotine containing e-cigarette, a prescription medicine***

332. Presently there is no nicotine containing prescription medicine entered on the ARTG. Accordingly, the importation (and relevantly supply) of a nicotine containing prescription medicine, such as a nicotine containing e-cigarette as an aid to stop smoking, is prohibited under the TG Act except where it:

- is imported by a medical practitioner in accordance with a Special Access B approval or Authorised Prescriber authority from the TGA;
- is imported by an individual for their or an immediate family member's use and is the subject of a prescription by a medical practitioner;
- comprises starting materials for subsequent manufacture by a compounding pharmacy; or
- is being imported by a third party to be held in a secure location pending supply pursuant to an approval or authority given to a medical practitioner by the Secretary of the Health Department (in practice the TGA within the Department).

### ***Special Access Scheme***

333. The Special Access Scheme allows certain health practitioners to access therapeutic goods that are not included in the ARTG for a single patient. The TGA has a responsibility to encourage the use of medicines that are included in the ARTG, as these products have been evaluated to ensure they meet strict standards of safety, quality and effectiveness. For this reason, it is expected that medical practitioners (prescribers) will have considered all clinically appropriate treatment options that are included in the ARTG before seeking to access nicotine containing e-cigarettes under the Special Access Scheme (SAS).

334. The TGA does not assure the quality, safety and effectiveness of unapproved products accessed through SAS and the prescriber and patient (via informed consent) accept responsibility for any adverse consequences of treatment.

335. The relevant category of Special Access Scheme for nicotine containing e-cigarettes is category B. SAS B is an application pathway through which a registered health practitioner may apply to the TGA for approval to prescribe an unapproved medicine for a patient under their care. The treatment for which nicotine containing e-cigarettes might be approved is a decision for the applicant medical practitioner in consultation with their patient. The applicant must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the ARTG are found not to be clinically suitable.



### ***Authorised Prescriber***

336. The Authorised Prescriber Scheme allows medical practitioners who become Authorised Prescribers to access and legally supply (including import) an unapproved therapeutic good or class of goods to appropriate patients.
337. Medical practitioners who wish to become Authorised Prescribers for nicotine in solution, salt or base form for inhalation for smoking cessation purposes must determine whether any suitable alternative marketed goods are available on the ARTG.
338. To become an Authorised Prescriber the medical practitioner must:
- Have the training and expertise appropriate for the condition being treated and the proposed use of the product
  - Be able to best determine the needs of the patient
  - Be able to monitor the outcome of therapy.
339. Medical practitioners who become Authorised Prescribers for nicotine for inhalation for smoking cessation purposes must:
- remain informed about changes to the benefits and risks to nicotine in the specified form for this purpose as they arise
  - consider the potential benefits and risks the unapproved good may offer each patient it is prescribed for
  - obtain written informed consent from each patient before prescribing
  - arrange supply of the goods directly through a sponsor or pharmacy
  - monitor the patient during and after use of the unapproved goods
  - give the TGA a supply report every six months for the periods ending 30 June and 31 December. The reports must be given to the TGA one calendar month after the reporting period
  - inform the TGA of adverse events associated with use of the good
  - meet any conditions which the TGA applies to the authority
  - comply with relevant state and territory law governing the supply of therapeutic goods.
340. The sponsor of the nicotine containing e-cigarette must:
- obtain a copy of the TGA approval letter from the medical practitioner prior to supplying the unapproved good (the nicotine for use in an e-cigarette / nicotine containing e-cigarette) to the medical practitioner
  - supply the unapproved good at their discretion
  - monitor the use of the goods, report adverse events and product defects and record the balance of risks and benefits

- provide the TGA with six-monthly reports on the supply of unapproved goods<sup>138</sup>
- inform the TGA of emerging safety concerns associated with the use of the unapproved goods, which they supply.

### **Commonwealth regulation of therapeutic goods – notification to the Comptroller-General of Customs**

341. Where *therapeutic goods* are unlawfully imported into Australia, those goods are ordinarily dealt with under powers granted to the Secretary under the TG Act, and those of the Australian Border Force (ABF) under the *Customs Act 1901* (Cth) (Customs Act). The outcome of those processes is that the imported goods may, after completion of the relevant process and absent a successful claim for the goods, be forfeited to the Crown as prohibited imports and subsequently destroyed.
342. Subsection 19B(7) of the TG Act provides that where therapeutic goods have been imported unlawfully, and the Secretary issues a notification to the Comptroller-General of Customs, the Customs Act will apply to those goods as if the goods were described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports.
343. The effect of the above is that the ABF may seize the goods and initiate a process under the Customs Act that can lead to the forfeiture and subsequent destruction of the therapeutic goods. This process involves the following steps:
- after detecting a potentially unlawful importation of therapeutic goods, the ABF refers the importation to the TGA for consideration;
  - the TGA sends a letter to the importer of the goods in question, providing a summary of the relevant law (including the personal importation scheme) and requesting that they provide evidence or information to demonstrate that the importation of the goods was lawful;
  - the TGA considers any evidence provided by the importer, along with the referral from the ABF, and comes to a view as to whether the importation was lawful or unlawful (if the importation is lawful, it is released to the importer);
  - if the importation is unlawful, a notification is made to the Comptroller, and a delegate of the Secretary provides the Comptroller with an evidentiary certificate issued under section 56A of the TG Act to serve as evidence that the importation was unlawful;
  - after receipt of the notification and evidentiary certificate, the ABF seize the goods under section 203B of the Customs Act and (unless there is a claim for the goods), the goods will subsequently be forfeited to the Crown under section 205C of the Customs Act;

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<sup>138</sup> S 47B(1)(c)(iii) of the *Therapeutic Goods Regulations 1990*.

- if the goods are forfeited to the Crown, they are destroyed.

### **Commonwealth regulation of therapeutic goods- advertising requirements**

344. Advertisements to medical practitioners and pharmacists (as well as other health care practitioners) of nicotine containing products for smoking cessation purposes are not subject to the advertising requirements of the TG Act. However, an advertisement to the public of such a product, which includes a schedule 4 substance, is unlawful; information, which is not promotional, is not an advertisement.

### **State and Territory regulation for human therapeutic use – prescription medicines**

345. Inclusion of a substance in schedule 4 of the Poisons Standard has the effect that it is a prescription medicine under state and territory poisons legislation. Their lawful supply is in accordance with a medical practitioner's prescription, generally dispensed by a pharmacist. Otherwise, only authorised health care practitioners can supply them such as in a hospital setting.

### **State and territory regulation - Advertising requirements for prescription medicines**

346. Only the Northern Territory and Tasmania prohibit the advertisement of a prescription medicine other than an advertisement to health practitioners.<sup>139</sup>

### **State and Territory regulation for human non-therapeutic use<sup>140</sup>**

347. Nicotine for non-therapeutic human use is regulated under state and territory poisons legislation. That legislation has been summarised at Annexure C. In summary, it is a criminal offence for a person to:

- use and/or possess non-therapeutic nicotine without authorisation in every state, other than South Australia (where only supply is unlawful); or
- supply non-therapeutic nicotine without a relevant licence, permit or other authority in every state other than Victoria (possessing, obtaining or using such substances is unlawful in Victoria unless licensed, authorised or permitted to do so, thereby bringing about a de facto prohibition on supply in that jurisdiction as well).

348. We understand that State and Territory jurisdictions have not granted any relevant authorisations to entities supplying non-medical nicotine, and that no relevant authorisations have been granted to individuals to possess or use non-medical nicotine.

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<sup>139</sup> Section 113 of the *Medicines, Poisons and Therapeutic Goods Act 2012* (NT) and s 44 of the *Poisons Regulations 2018* (Tas).

<sup>140</sup> Whilst the TG Act does not apply to nicotine containing products for non-therapeutic use the *Competition and Consumer Act 2010* applies.

349. However, there is no prohibition on the importation of non-therapeutic nicotine at the Commonwealth level. As a result, importations of non-therapeutic nicotine must currently be allowed to enter Australia. This is despite the fact that the importer will usually, by possessing, using or supplying the imported nicotine, contravene the law of their state or territory of residence.

## Annexure C – State and Territory regulation of nicotine supply, use and possession

Table 10: State and Territory regulation of nicotine supply, use and possession

### Section 1 - Regulation of supply, use and possession of nicotine for therapeutic use

State	Regulatory status	Supply	Use or administration	Possession
ACT	<p>Prescription only medicine (s 11(2), ACT Poisons Act)</p> <p>Medicine (s 11(1), ACT Poisons Act)</p> <p>Declared substance (s 25, ACT Poisons Act)</p>	<p>Supply prohibited unless person is authorised (s 26, ACT Poisons Act)</p> <p>Supply is authorised for a range of classes of medical practitioners, including doctors and pharmacists (where dispensing) (r 30(1) and Schedule 1, ACT Poisons Regulations)</p>	<p>Administration to self or someone else is prohibited unless person is authorised (s 37, ACT Poisons Act)</p> <p>A person will be authorised to administer to themselves if they obtained the medicine from a person authorised to supply it (r 360(2)(b), ACT Poisons Regulations)</p>	<p>Possession prohibited unless person is authorised (s 36, ACT Poisons Act)</p> <p>A person will be authorised if they obtained the medicine from a person authorised to supply it (r 370(1), ACT Poisons Regulations)</p>

<b>State</b>	<b>Regulatory status</b>	<b>Supply</b>	<b>Use or administration</b>	<b>Possession</b>
<b>NSW</b>	Restricted substance (s 4(1) of the NSW Poisons Act, read with r 3 of the NSW Poisons List)	Supply prohibited by persons other than those listed at s 10(4) of the NSW Poisons Act (s 10(3), NSW Poisons Act)  Persons authorised include medical practitioners and pharmacists on prescription	No prohibition on use	No prohibition on possession
<b>NT</b>	Schedule 4 substance (ss 7 and 14, NT Poisons Act)	Must not supply unless authorised (e.g., per Schedule 4 authorisation issued under s 124, NT Poisons Act) (s 40, NT Poisons Act)	Must not use unless authorised (s 41, NT Poisons Act)	Must not possess unless authorised (s 39, NT Poisons Act)
<b>Qld</b>	Restricted drug (r 5, r	Must not dispense,	No express prohibition on	Must not possess

State	Regulatory status	Supply	Use or administration	Possession
	7 and Appendix 9, QLD Poisons Regulations )	issue, prescribe or sell unless endorsed to do so (r 146(3), QLD Poisons Regulations)  Persons endorsed to do so include doctors (r 161) and pharmacists (r 171)	use, however prohibition of unauthorised possession would preclude unauthorised use	unless endorsed to possess (r 146(1), QLD Poisons Regulations )  A person who lawfully obtains may possess for the time needed to use for the relevant medical purpose (r 205(1))
SA	Prescription drug (r 3(2) and r 6, SA Poisons Regulations )	Wholesale and retail supply prohibited unless authorised (r 18(1a), (1b), 1c), SA Poisons Regulations)  Persons authorised include registered health	No express prohibition on use, however prohibition of unauthorised possession would preclude unauthorised use	Possession prohibited unless authorised (r 18(3), SA Poisons Regulations )  Persons authorised include persons to whom drug has been lawfully

State	Regulatory status	Supply	Use or administration	Possession
		practitioners and pharmacists on prescription		prescribed or supplied
<b>TAS</b>	Restricted substance (s 3(1) and 14, TAS Poisons Act)	Sale and supply prohibited unless appropriately authorised (s26(1B), TAS Poisons Act)  Persons authorised include medical practitioners and pharmacists	No prohibition on use	No prohibition on possession (as not included in the <a href="#">Poisons (Declared Restricted Substances) Order 2017</a> (TAS) for the purposes of s 36 of the TAS Poisons Act)
<b>VIC</b>	Schedule 4 poison (s 4(1), VIC Poisons Act)	Must not sell or supply by wholesale or retail unless authorised or licensed to do so (ss 23, 26, VIC Poisons Act)  Persons authorised include	Must not self-administer a Schedule 4 poison unless it was lawfully supplied to them (r 105, VIC Poisons Regulations)	Must not possess unless authorised or licensed to do so (s 36B(2), VIC Poisons Act)  Persons authorised include



State	Regulatory status	Supply	Use or administration	Possession
		<p>medical practitioners and pharmacists (Parts 5 and 6, VIC Poisons Regulations)</p>		<p>persons to whom a Schedule 4 poison has been lawfully supplied by a medical practitioner, pharmacist etc. (r 7, VIC Poisons Regulations)</p>
<p><b>WA</b></p>	<p>Schedule 4 poison (s 3, WA Poisons Act, r 6, WA Poisons Regulations)</p>	<p>Supply prohibited unless under an appropriate licence or a professional authority (s 14(1), WA Poisons Act)</p> <p>Health professionals are authorised to administer, possess, supply etc. within scope of their profession</p>	<p>No express prohibition on use, however prohibition of unauthorised possession would preclude unauthorised use</p>	<p>Possession prohibited except for certain classes of persons (s 14(4), WA Poisons Act)</p> <p>Classes of persons who may possess include persons who were prescribed the substance and possess it for the</p>

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State	Regulatory status	Supply	Use or administration	Possession
		and in accordance with law (s 25, WA Poisons Act)		purpose of using it per practitioner directions (s 14(4)(d))

## Section 2 – Regulation of supply, use and possession of nicotine for non-therapeutic use

State	Regulatory status	Supply	Use or administration	Possession
<b>ACT</b>	Dangerous poison (s 12(2), ACT Poisons Act) Declared substance (s 25, ACT Poisons Act)	Supply prohibited unless person is authorised (s 26, ACT Poisons Act)	Administration to self or someone else is prohibited unless person is authorised (s 37, ACT Poisons Act)	Possession prohibited unless person is authorised (s 36, ACT Poisons Act)
<b>NSW</b>	Schedule 7 substance (r 3(2)(c) of the NSW Poisons Regulations, read with r 3 of the NSW Poisons List)	Supply prohibited unless person holds an authority to supply, and person being supply holds an authority to obtain (r 20(2), NSW Poisons Regulations)	A person must not obtain or use unless they hold an authority to obtain or use (r 20(1), NSW Poisons Regulations)	No prohibition on possession
<b>NT</b>	Schedule 7 substance (ss 7 and 14, NT Poisons Act)	Must not supply unless appropriately licensed or authorised	Use is prohibited unless the use is authorised under a relevant authorisation	No prohibition on possession

		(s 42, NT Poisons Act) Must not supply to a person unless satisfactory evidence provided that use is lawful (s 43, NT Poisons Act)	(s 44(2), NT Poisons Act)	
<b>Qld</b>	Regulated poison (Para 3 of Appendix 7 as read with Appendix 9, QLD Poisons Regulations )	Must not sell unless person holds a relevant approval or falls within certain specified classes of person (r 271, QLD Poisons Regulations)	Must not obtain or use unless person holds a relevant approval or falls within certain specified classes of person (r 271, QLD Poisons Regulations)	Must not possess unless person holds a relevant approval or falls within certain specified classes of person (r 271, QLD Poisons Regulations)
<b>SA</b>	S7 poison (r 3(2), SA Poisons Regulations )	Wholesale and retail supply prohibited unless person is a health practitioner or pharmacist, or under relevant	No prohibition of personal use (SA has advised that prohibition on domestic use under s 27, SA Poisons Act, read with r 30, SA Poisons Regulations,	No prohibition on possession

		licence (ss 14 and 15, SA Poisons Act, read with regs 11 and 12, SA Poisons Regulations)	would not apply)	
<b>TAS</b>	Prescribed dangerous poison (r 91(1) of the TAS Poisons Regulations and s 3(1) of the TAS Poisons Act) <sup>141</sup>	Sale and supply prohibited unless appropriately authorised (s 91(11), TAS Poisons Regulations)	No specific prohibition on use, however prohibition on possession would preclude use in this case	Possession prohibited unless appropriately authorised (s 91(11), TAS Poisons Regulations)
<b>VIC</b>	Listed regulated poison (r 5(1), VIC Poisons Regulations and Part 2, VIC Poisons List)	Must not sell or supply by wholesale or retail unless authorised or licensed to do so (ss 23, 26, VIC Poisons Act)	Must not purchase or otherwise obtain or use unless authorised, licensed or permitted to do so (r 148, VIC Poisons Regulations)	Must not possess unless authorised, licensed or permitted to do so (r 148, VIC Poisons Regulations)
<b>WA</b>	Schedule 7 poison (s 3, WA Poisons	Supply prohibited unless done	Use prohibited without relevant	Possession prohibited without

<sup>141</sup> The definitions in Tasmania apply due to the inclusion of Nicotine in Appendix J to the Poisons Standard, rather than the Schedule 7 entry or by specification under State/Territory law (as is the case for the other jurisdictions).

	Act, r 6, WA Poisons Regulations )	under an appropriate licence (s 16(1), WA Poisons Act)	authority under WA law (s 17(2), WA Poisons Act)	relevant authority under WA law (s 17(2), WA Poisons Act)
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## Section 3 – Relevant legislation and instruments

State	Defined Term	Legislation and instruments
ACT	ACT Poisons Act	<a href="#"><i>Medicines, Poisons and Therapeutic Goods Act 2008</i></a> (ACT)
	ACT Poisons Regulations	<a href="#"><i>Medicines, Poisons and Therapeutic Goods Regulation 2008</i></a> (ACT)
NSW	NSW Poisons Act	<a href="#"><i>Poisons and Therapeutic Goods Act 1966</i></a> (NSW)
	NSW Poisons Regulations	<a href="#"><i>Poisons and Therapeutic Goods Regulations 2008</i></a> (NSW)
	NSW Poisons List	<a href="#"><i>Poisons and Therapeutic Goods (Poisons List) Proclamation 2016</i></a> (NSW)
NT	NT Poisons Act	<a href="#"><i>Medicines, Poisons and Therapeutic Goods Act 2012</i></a> (NT)
QLD	QLD Poisons Regulations	<a href="#"><i>Health (Drugs and Poisons) Regulation 1996</i></a>
SA	SA Poisons Act	<a href="#"><i>Controlled Substances Act 1984</i></a> (SA)
	SA Poisons Regulations	<a href="#"><i>Controlled Substances (Poisons) Regulations 2011</i></a> (SA)
TAS	TAS Poisons Act	<a href="#"><i>Poisons Act 1971</i></a> (TAS)
	TAS Poisons Regulations	<a href="#"><i>Poisons Regulations 2018</i></a> (TAS)
VIC	VIC Poisons Act	<a href="#"><i>Drugs, Poisons and Controlled Substances Act 1981</i></a> (VIC)
	VIC Poisons Regulations	<a href="#"><i>Drugs, Poisons and Controlled Substances Regulations 2017</i></a> (VIC)
	VIC Poisons List	<a href="#"><i>Poisons Code</i></a> (as made by the Minister and published on the Victorian Government website)

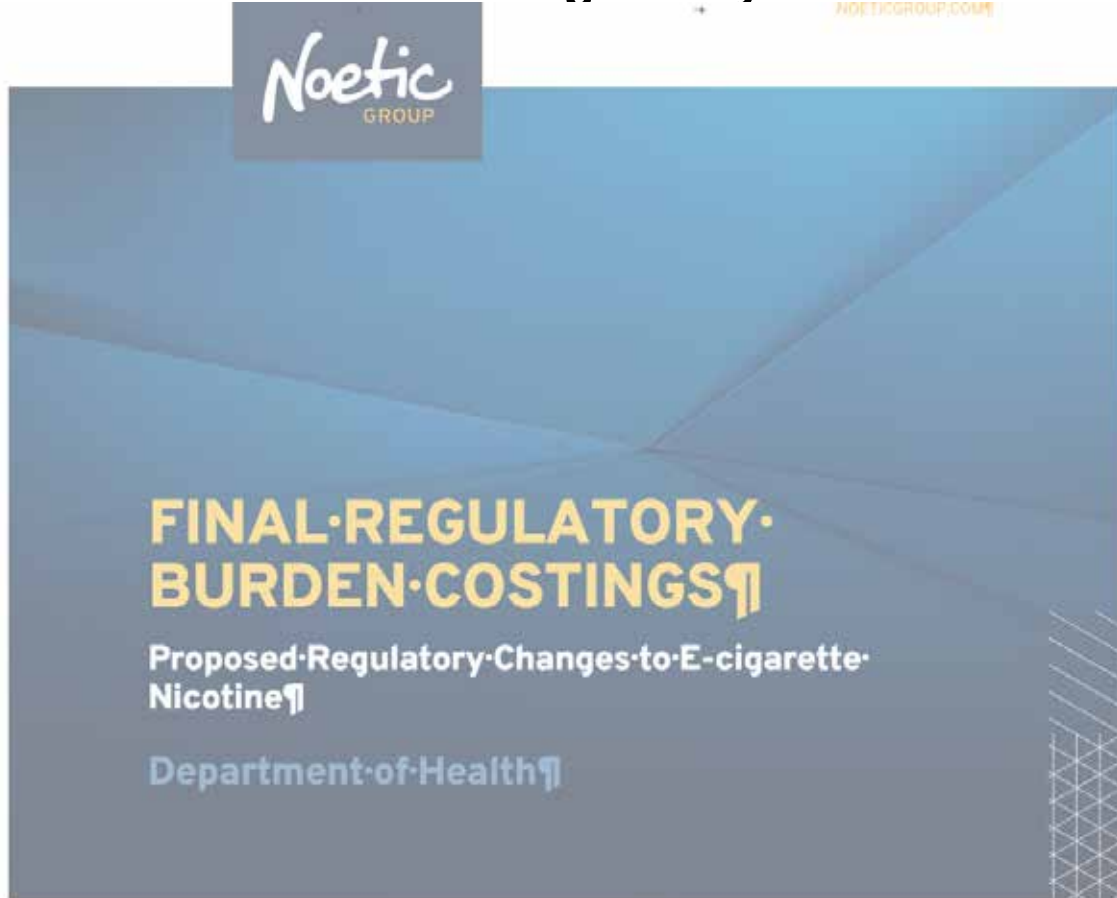
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State	Defined Term	Legislation and instruments
WA	WA Poisons Act	<a href="#"><i>Medicines and Poisons Act 2014</i></a> (WA)
	WA Poisons Regulations	<a href="#"><i>Medicines and Poisons Regulations 2016</i></a> (WA)



## Annexure D – Noetic Regulatory Burden





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# Executive Summary

## Background

There has been growing concern among the Australian Government about the direct harms that

e-cigarettes pose to human health and the increase in their usage, particularly among adolescents and young adults. As such, the objectives of Government actions are to:

- § arrest the recent rapid increase in use of e-cigarettes containing nicotine by adolescents and young adults
- § provide to patients who want to stop smoking efficacious support that is not already available (such as the Quit program)- likely in the form of medical practitioner support, including considering whether to prescribe e-cigarettes containing nicotine
- § reduce the likelihood of child poisoning by accidental consumption of nicotine.

In order to achieve the above, four key options are being considered. Options include maintaining the status quo (Option 1), Public awareness campaign (Option 2), clarification of the entry of nicotine in the Poisons Standard (including requirement for child resistance closure container) (Option 3) and Options 2 and 3 combined (Option 4).

## Purpose of this Report

The purpose of this report is to provide a quantification of the regulatory impact of the proposed clarification to the regulation of nicotine to inform the Regulation Impact Statement (RIS) prepared by the Department of Health.

## Approach

The modelling detailed in this report was conducted in accordance with the Australian Government's requirements and the Office of Best Practice Regulation's (OBPR) guidance for the calculation of regulatory costs. The Noetic Group (Noetic) relied on advice provided by the Government (Department of Health) and their own professional judgement to determine the time taken to undertake the activities associated with the implementation of the proposed regulatory clarifications.

## Conclusion

As per OBPR guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost. The following table provides the average estimated regulatory compliance costs arising from the proposed regulatory clarification.

Table ES1. Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) (\$million)				
Change in costs	Business \$	Community Organisation \$	Individual \$	Total change in costs
<b>Option 1</b>				
Status quo: Current therapeutic goods regulatory frameworks are appropriate - no clarification is required				
<b>Option 2</b>				
Public awareness campaign (stop initiation/dependence on e-cigarette/smoking cessation)				
<b>Option 3</b>	\$0.05		\$4.93	\$4.98
Clarification of the entry for nicotine in the Poisons Standard (including requirement for child resistant closure container)				
<b>Option 4</b>	\$0.05		\$4.93	\$4.98
Options 2 and 3 combined				

## General

### Background

#### Need for regulatory changes to nicotine

Within Australia, and internationally, there has been growing concern about the direct harms that e-cigarettes pose to human health, their impacts on nicotine addition, smoking initiation and cessation, uptake amongst youth, and dual use with conventional tobacco products. There is a concern that the existing controls governing the marketing and use of e-cigarettes within Australia may not be providing adequate protection to the community's public health.

In the World Health Organization's (WHO) '2019 Report on the Global Tobacco Epidemic', WHO recommended that Member States that have not banned Electronic Nicotine Delivery

Systems should consider regulating them as harmful products.<sup>142</sup> Research has demonstrated that e-cigarette use is relatively low in countries with strict regulatory controls.<sup>143</sup>

It is noted that there has been a widespread expansion of e-cigarette use internationally as well as domestically. The Australian Institute of Health and Welfare’s (AIHW) ‘National Drug Strategy Household Survey 2019’ reported that e-cigarette usage has significantly increased for both smokers and non-smokers between 2016 and 2019. There has also been a large increase in the use of e-cigarettes, particularly in the 14-18, 18-24- and 25-29-year age groups, that have seen a 2-4 fold increase during that time period.<sup>144</sup>

This growth in the use of e-cigarettes is concerning as nicotine is highly addictive and e-cigarette use is likely to have adverse health consequences. Nicotine can cause substantial negative cardiovascular, respiratory and reproductive effects.<sup>145</sup> It is highly toxic and can have adverse effects on foetal and adolescent development – ingestion of just 1-2 mL of nicotine in e-cigarette fluid refills can kill a toddler.<sup>146</sup> There is also clinical evidence that points to heart rate increases alongside the use of nicotine and increases in systolic blood pressure.<sup>147</sup> Growing clinical evidence also suggests that exposure to e-liquids can result in seizures, anoxic brain injury and vomiting.<sup>148</sup>

There is some limited evidence that suggests that e-cigarettes may be an effective smoking cessation aid. Observational studies have resulted in moderate evidence that more frequent use of e-cigarettes is associated with an increased likelihood of cessation. However, from a randomised control trial, there was insufficient evidence found about the effectiveness of e-cigarettes as a smoking cessation aid.<sup>149</sup>

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<sup>142</sup> [https://www.who.int/tobacco/global\\_report/en/](https://www.who.int/tobacco/global_report/en/).

<sup>143</sup>

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25372](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25372).

<sup>144</sup> <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/contents/table-of-contents>.

<sup>145</sup>

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25371](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25371).

<sup>146</sup>

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/House/Health\\_Aged\\_Care\\_and\\_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25372](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/ElectronicCigarettes/Report/section?id=committees%2freportrep%2f024115%2f25372).

<sup>147</sup> National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems. (2018) Public Health Consequences of E-Cigarettes. Washington (DC): National Academies Press (US). [Online]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507163/>.

<sup>148</sup> Byrne, Brindal, Williams et al. “E-cigarettes, smoking and health: A Literature Review Update” CSIRO, 2018.

<sup>149</sup> <https://pubmed.ncbi.nlm.nih.gov/29894118/>.

## Current requirements in Australia

The nature of the regulatory framework that applies to e-cigarette nicotine products depends on whether the intended use is therapeutic<sup>150</sup> (smoking cessation) or non-therapeutic (often referred to as recreational, however, will be referred to as non-therapeutic for the remainder of this report). Where the purpose of the use of e-cigarette nicotine is therapeutic, the importation of e-cigarette nicotine (within a device or otherwise) is affected by the *Therapeutic Goods Act 1989 (Cth)* (TG Act). The possession, use and supply of e-cigarette nicotine is also subject to the regulations concerning prescription-only substances under State and Territory poisons legislation. While there is currently no prohibition on the import of e-cigarette nicotine at the Commonwealth level, if the purpose of e-cigarette nicotine is non-therapeutic, State and Territory poisons legislation restricts its supply and, (in all states other than South Australia) possession and use.

The Commonwealth Poisons Standard regulates substances including nicotine. Decisions relating to the scheduling of substances in the Poisons Standard are made by a senior medical officer acting as the delegate of the Secretary of the Department of Health. These decisions are made in accordance with the requirements of the TG Act including the Scheduling Policy Framework for Medicines and Chemicals endorsed by the Australian Health Ministers Advisory Council. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons. The Poisons Standard is the legal title of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The scheduling classification sets the level of control on the availability of poisons. In making decisions concerning the scheduling of substances under the Poisons Standard, delegate must have regard to the factors set out at section 52E of the TG Act, being:

- a. the risks and benefits of the use of the substance;
- b. the purposes for which the substance is to be used and the extent of use of the substance;
- c. the toxicity of the substance;
- d. the dosage, formulation, labelling, packaging and presentation of the substance;
- e. the potential for abuse of the substance; and
- f. any other matters that the Secretary considers necessary to protect public health.

There are two schedules and two appendices within the SUSMP that are relevant to the regulation of nicotine:

- § **Schedule 4 (prescription only medicine)** – these medicines are only available for purchase from pharmacies with presentation of a valid prescription (i.e. provided by a medical or dental practitioner).

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<sup>150</sup> Therapeutic use is defined as ‘use in or in connection with’, among other things, ‘preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons’ or ‘influencing, inhibiting or modifying a physiological process in persons’ in the TG Act.



- § **Schedule 7 (dangerous poison)** – these poisons, which have a high potential for causing harm, are only available to specialised or authorised users who have the skills necessary to handle them safely and special regulations restricting their availability, possession, storage or use may apply.
- § **Appendix J** - provides a list of poisons included in Schedule 7 where additional specified conditions apply to their availability and use.
- § **Appendix F** – provides warning statements and general safety directions for poisons.

If nicotine is prepared for human therapeutic use, it is included in Schedule 4 (except when it is used as an aid for smoking cessation, i.e. nicotine patches or gum). If it is prepared for non-therapeutic use, it is included in Schedule 7 and Appendixes F and J (except in tobacco prepared and packed for smoking).

## Importation of e-cigarette nicotine under the TG Act

Currently, there is no nicotine-containing-product entered on the Australian Register of Therapeutic Goods (ARTG) as a prescription only medicine. There are, however, nicotine replacement therapies such as gums, mists and patches listed or included as registered over-the-counter medicines. As such, when nicotine is intended for therapeutic use, its importation is restricted under the TG Act to where the nicotine:

- § is imported under the personal importation scheme (by mail or because the importer is a passenger on a ship or aeroplane) in accordance with a prescription by a medical practitioner
- § comprises starting materials for subsequent manufacture by a compounding pharmacy
- § is being imported by a third party to be held in a secure location pending supply in accordance with an approval or authority given to a medical practitioner by the Secretary of the Department of Health (the Department) (in practice, the TGA, which is a part of the Department).

A medicine containing a substance in Schedule 4 may only be lawfully supplied under state and territory law if in accordance with a prescription. A good containing a substance in Schedule 7 substance is a dangerous poison for which generally state and territory law makes personal use or possession unlawful. Accordingly, because:

- § imports of nicotine for non-therapeutic use are not in Schedule 4 of the Poisons Standard, and
- § the ‘personal importation scheme’ under the therapeutic goods framework:
  - + does not exclude its use for the importation of a product including a Schedule 7 substance; and
  - + only requires a prescription to support the importation on medicines containing Schedule 4 substances; and
- § the sale of nicotine containing e-cigarettes is unlawful in every state and territory

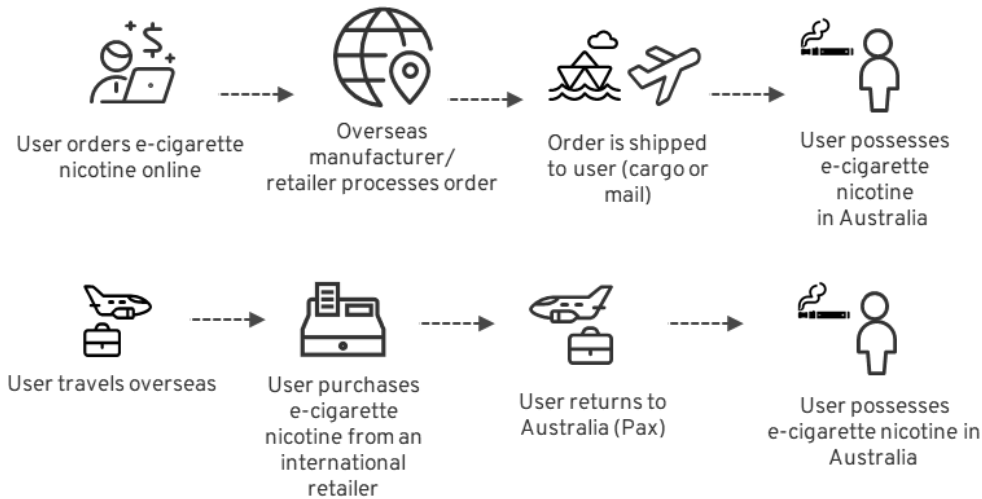
consumers have turned to importation (on a large scale) to purchase nicotine containing e-cigarettes for non-therapeutic use. This is despite the fact that the importer will usually, by possessing, using or supplying the imported nicotine, contravene the law of their state or territory of residence.

Where therapeutic goods are unlawfully imported into Australia, those goods are ordinarily dealt with under powers granted to the Secretary under the TG Act and those of the Australian Border Force (ABF) under the *Customs Act 1901* (Cth) (Customs Act). The outcome of these processes is that the imported goods may, after completion of the relevant processes (detainment, investigations etc.) and in absence of a successful claim for the goods, be forfeited to the Crown as prohibited imports and destroyed.

However, present state and territory laws regulating the domestic sale of e-cigarettes nicotine are impacted by the ABF currently having no legal basis to intercept these products at the border. Users can therefore import e-cigarettes into Australia relatively easily (without a prescription) by ordering online from an overseas retailer and bypass

the state/territory restrictions on domestic sale. Due to these circumstances, consumers/patients will be unlikely to visit a doctor to be prescribed nicotine-cigarette nicotine when they can order it online (overseas retailer) themselves or do not need to/will not declare e-cigarette nicotine purchased overseas when they return from overseas travel. Therefore, the current consumer pathways are the following:

**Figure 1: Current consumer pathways**



## Proposed regulatory clarification options

### Overview

Option 1 in a regulatory costing is the status quo and provides the regulatory cost baseline for the proposed variations to the existing regulatory framework, as detailed below.

### Option 2 – Public Awareness Campaign

The Australian Government is proposing to undertake a campaign which aims to reduce the harmful effects of nicotine products, through targeted education for adolescents and young adults, as well as those using e-cigarettes as a smoking cessation aid.

### Option 3 – Clarifications to the Poison Standard ('Scheduling')

The Delegate is proposing clarification of the entry in the Poison Standard of nicotine for which there is no proposed sunset date. This option also includes the requirement for child resistant closure for nicotine liquid containers. The proposed amendment of the current Poison Standard in relation to nicotine is detailed in the table below:

Table 1. Proposed amendment of the current Poison Standard in relation to nicotine.

Location	Current provision	Proposed provision
<b>Schedule 4</b>	NICOTINE in preparations for human therapeutic use <b>except</b> for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.	NICOTINE in preparations for human use <b>except</b> : <ul style="list-style-type: none"> <li>a. in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking; or</li> <li>b. in tobacco prepared and packed for smoking</li> </ul>
<b>Schedule 6</b>	NICOTINE in preparations containing 3 per cent or less of nicotine when labelled and packed for the treatment of animals.	
<b>Schedule 7</b>	NICOTINE except: <ul style="list-style-type: none"> <li>a. when included in Schedule 6;</li> <li>b. in preparations for human therapeutic use; or</li> <li>c. in tobacco prepared and packed for smoking.</li> </ul>	NICOTINE except: <ul style="list-style-type: none"> <li>a. when included in Schedule 4;</li> <li>b. in preparations for oromucosal or transdermal administration for human therapeutic use as an aid in withdrawal from tobacco smoking</li> <li>c. in tobacco prepared and packed for smoking</li> </ul>
<b>Appendix D, Item 5</b>		Nicotine
<b>Part 2-4</b>		Required child resistant closure for the container.

Option 4 – Options 2 and 3 combined (‘combined’)

## Purpose of this report

The purpose of this report is to provide a quantification of the regulatory impact of the proposed clarification to the regulation of nicotine to inform the Regulation Impact Statement (RIS) prepared by the Department of Health.

## Approach

The modelling detailed in this report was conducted in accordance with the Office of Best Practice Regulation’s (OBPR) guidance for the calculation of regulatory costs and the approach was briefed and agreed in principle by the OBPR.

The below activities were undertaken to inform the development of the Regulatory Costing:

- § undertook desktop research to understand the current regulations for nicotine in Australia
- § identified changes in activities which relate to the clarification of the entry of nicotine in the Poisons Standard (henceforth referred to as 'scheduling change'), focusing on administrative and substantive compliance costs
- § identified regulatory touch-points for the proposed changes to the regulation (including second-order touch-points necessary to achieve the sought outcomes of the proposed regulatory changes)
- § determined the respective populations impacted by identified touch-points (i.e. doctors, pharmacists, patients/consumers, industry etc.) and mapped pathways and requirements
- § utilised existing datasets to determine current and future (growth) population numbers and to quantify frequency and time required for each activity
- § determined appropriate labour costs using the Australian New Zealand Standard Industrial Classification (ANZSIC) groupings.

The above activities were supported by consultation workshops with government representatives from the TGA, the Office of Drug Control (ODC) in the Department of Health and the ABF in the Department of Home Affairs. These activities were undertaken to gain further information, identify likely response pathways and to test and validate some of Noetic's assumptions.

Noetic also engaged OBPR at the beginning of the project to confirm the proposed approach and seek advice or direction regarding assumptions, qualifications, and inputs, which was followed by a further meeting with OBPR to discuss the Draft Final Report on 18 November 2020.

Specifically, Noetic has considered the following options in the preparation of the regulatory costings:

- § Option 1 – Status Quo: No clarification of the therapeutic goods regulatory framework is required; the current regulations (including State and Territory) are appropriate
- § Option 2 – Campaign to address the information gaps and to increase awareness among:
  - + adolescents and young adults of the health risks of nicotine addiction and the use of e-cigarettes including the risk of acting as a gateway to smoking
  - + smokers of the evidence of the effects of smoking and of the benefits of smoking cessation.
- § Option 3 – TGA amendments to the Poison Standard from 1 October 2021.
- § Option 4 – Options 2 and 3 combined.

# The Regulatory Costing

## Costing model

### Overview

The development of the regulatory costing model was undertaken in accordance with the OBPR Guidance Note: 'Regulatory Burden Measurement Framework', dated 30 March 2020. Costs were estimated for administrative compliance costs only, as no substantive

costs were identified. Delay costs (application and approval delays) were determined to be out-of-scope.

The labour cost formula was used to determine these administrative compliance costs: price x quantity (or in its more expanded version: (Time required × Labour cost) × (Times performed × Number of businesses or community organisations × Number of staff)).

As detailed earlier in this report, various engagement activities have been undertaken to identify the first- and second-order touchpoints for stakeholder groups to allow the arising regulatory burden to be quantified.

## Labour cost

The Australian Bureau of Statistics (ABS) publishes ‘Average Weekly Earnings’ semi-annually. As of 14 September 2020, the latest dataset is May 2020.<sup>151</sup> Given that users, healthcare providers and potential domestic wholesalers/importers could be based in any state/territory, the national dataset was used. The relevant table is Table 10H (‘Average Weekly Earnings, Industry, Australia (Dollars) - Original - Persons, Full Time Adult Total Earnings’ (includes overtime)). Three Australian and New Zealand Standard Industrial Classification (ANZSIC) divisions were considered by Noetic as being relevant to the particular activities being costed:

- § Wholesale Trade (ANZSIC Division F). Industry subdivisions are: Basic Material Wholesaling, Machinery and Equipment Wholesaling, Motor Vehicle and Motor Vehicle Parts Wholesaling, Grocery, Liquor and Tobacco Product Wholesaling, Other Goods Wholesaling (which incorporates Pharmaceutical and toiletry good manufacturing) and Commission-Based Wholesaling. As at September 2020, the current figure for weekly earning is \$1626.70.
- § Professional, Scientific and Technical Services (ANZSIC Division M). Industry subdivisions are: Professional, Scientific and Technical Services (Except Computer System Design and Related Services), and Computer System Design and Related Services. As at September 2020, the current figure for weekly earning is \$1984.80.
- § Health Care and Social Assistance (ANZSIC Division Q). Industry subdivisions are: Hospitals, Medical and Other Health Care Services, Residential Care Services, and Social Assistance Services. As at September 2020, the current figure for weekly earning is \$1672.40.

It was assessed by Noetic that the Wholesale Trade category was the most appropriate division for potential domestic wholesalers/importers. To determine the average hourly cost, this weekly earnings figure (\$1626.70) is divided by the average number of total hours worked (includes overtime) for full-time non-managerial employees (the ‘All Industries’ category has been used) (39.40 hours).<sup>152</sup> In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the nonwage labour on-costs and overhead costs. The arising calculation is shown below.

<sup>151</sup> Australian Bureau of Statistics, 6302.0 - Average Weekly Earnings, Australia, May 2020. <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6302.0May%202020?OpenDocument>.

<sup>152</sup> Australian Bureau of Statistics, 6306.0 - Employee Earnings and Hours, Australia, May 2018. <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument>.

$$(\$1626.70/39.40)*1.75 = \$72.25^{153}$$

It was assessed by Noetic that the Professional, Scientific and Technical Services was the more appropriate industry division for potential sponsors because it is most likely to include the regulatory staff who would undertake the sponsor activities required by the TGA.

For September 2020, the figure for weekly earnings is therefore \$1984.80. To determine the average hourly cost, this figure is divided by the average number of total hours worked (includes overtime) for full-time non-managerial employees (the 'All Industries' category has been used) (39.40 hours).<sup>154</sup> In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the nonwage labour on-costs and overhead costs. The arising calculation is shown below.

$$(\$1984.8/39.40)*1.75 = \$88.16^{155}$$

It was assessed by Noetic that the Healthcare and Social Assistance category was not representative of doctors' wages. This category incorporates a broad grouping of healthcare workers and thus the hourly rate for doctors is likely to be skewed by lower-earning professions included in this category. Rather, Noetic has costed doctors' time at \$84.26 per hour.<sup>156</sup>

In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the nonwage labour on-costs and overhead costs. The arising calculation is shown below.

$$\text{Doctors: } \$84.26*1.75 = \$147.46$$

An individual's (user's) time, while not in paid employment (such as during leisure time), has been costed at \$32.00 per hour, as per OBPR guidance. In accordance with OBPR guidance a multiplier is not applied to this figure.

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<sup>153</sup> By way of comparison, the suggested hourly labour rate by OBPR is \$73.05 as compared to a value of \$72.25 as calculated above.

<sup>154</sup> Australian Bureau of Statistics, 6306.0 - Employee Earnings and Hours, Australia, May 2018 <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument>.

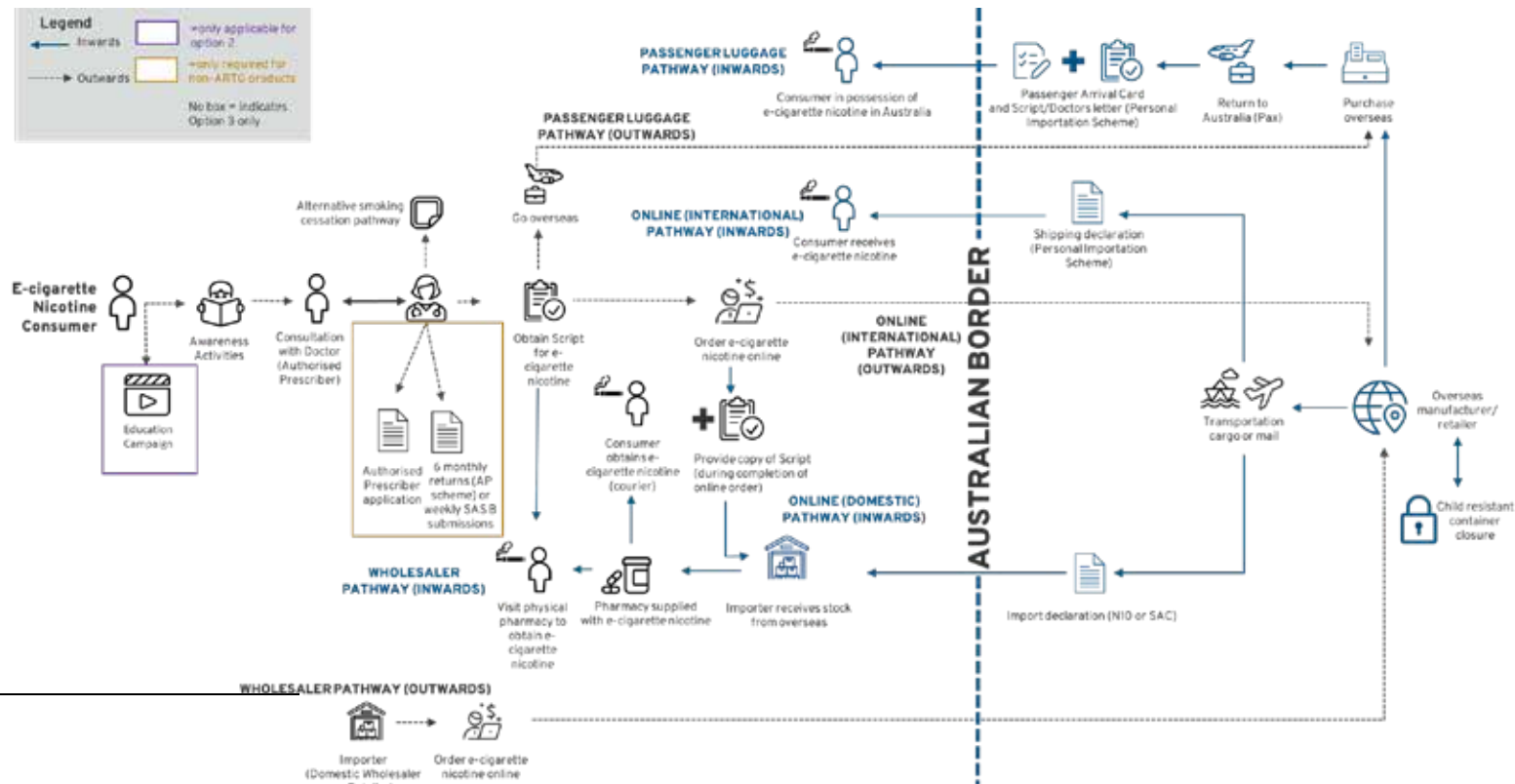
<sup>155</sup> By way of comparison, the suggested hourly labour rate by OBPR is \$73.05 as compared to a value of \$88.16 as calculated above.

<sup>156</sup> [https://www.payscale.com/research/AU/Job=General\\_Practitioner/Salary](https://www.payscale.com/research/AU/Job=General_Practitioner/Salary) (click on 'Show hourly rate' link)

# Regulatory Impact

## Overview of regulatory impact analysis















Figure 1. Overview of regulatory pathway analysis<sup>157</sup>



<sup>157</sup> A slight variation to the pathways shown is for a user to obtain the script from a non-AP GP. This script can only be used for the shown inwards pathways involving the Personal Importation Scheme.

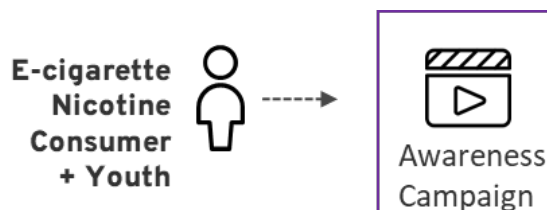
Noetic has identified a series of activities that will be undertaken by doctors, pharmacists, e-cigarette nicotine users and future domestic wholesalers/importers as a result of the proposed regulatory changes. While some of these activities and the affected populations are common across multiple options, others relate to single option. The below table outlines the variations in activities across the five options (noting populations may differ).

**Table 2. Variations in regulatory activities by options**

REGULATORY ACTIVITY	Option 1 Status Quo	Option 2 Awareness Campaign	Option 3 Scheduling Change	Option 4 Options 2 and 3 Combined
Awareness				
Education				
Consultation with Doctor (to obtain script)				
Activities relating to obtaining e-cigarette nicotine (physical and online pharmacy visits)				
Authorised Prescriber Scheme + Special Access Scheme B				
Import Permit				
Import Declaration				
Register e-cigarette nicotine on the Australian Register for Therapeutic Goods (ARTG)				



## Option 2 (Awareness campaign)



### Overview

Under Option 2, the Commonwealth (working with states and territories) is proposing to conduct an awareness campaign to address the information gaps and to increase awareness among:

- § adolescents and young adults of the health risks of nicotine addiction and the use of e-cigarettes including the risk of acting as a gateway to smoking
- § smokers of the evidence of the effects of smoking and of the benefits of smoking cessation.

Option 2 involves targeted awareness and education activities for users. Because the domestic supply of nicotine containing e-cigarettes is presently unlawful, the behaviour sought to be influenced is that of users; the Department of Health considers it would be inappropriate to expand the campaign to include messages for persons other than current and potential (youth) users.

The National Tobacco Campaign (the NTC) is a vital component of the Australian Government's suite of tobacco control initiatives. Its aim is to work in concert with other tobacco control and prevention activities, including policies and legislative measures, to reduce the health burden of smoking on the Australian community. The campaign would aim to convince adolescents, young adults and smokers to change their behaviours. For adolescents and young adults, the focus would be on ceasing/reducing the uptake of e-cigarette nicotine (avoid the ON RAMP for current non-smokers especially youth). For current smokers, the desired behavioural change is the cessation of smoking (provide the OFF RAMP for smokers).

Noetic notes that prior to the development of the campaign, consultation with secondary school and tertiary providers would be undertaken. This would ensure the campaign (likely using the popular social medium channels for the target audience - online platforms and digital media channels) would be promoted within secondary schools and tertiary education settings.

For smokers, the next iteration of the NTC would build on aspects of the current campaign, but would be more targeted, incorporating research and consultation on the most common profiles of current smokers and utilising the most accessible medium and message for them. It is also noted that this campaign would encourage smokers to discuss their smoking addiction with their medical practitioner.

As users will likely be exposed to campaign material as part of their day-to-day activities, the Department communications will form but part of the broader messaging consumed in

any given day. Furthermore, it is likely that the delivery of information will be incorporated within current tertiary settings and thus will not increase the contact hours for teachers nor students but rather form part of day-to-day activities. As the above activities do not result in any additional time imposed on (potential) users, there is no additional regulatory cost associated with this option.<sup>158</sup>

## Option 3 (scheduling)

The following regulatory impacts are common across all Option 3 Pathways (see Figure 1).

### User, doctor, and wholesaler/importer awareness

#### Overview



For Option 3, e-cigarette nicotine users and doctors will need to be aware of the proposed regulatory changes, while some future importers (suppliers) will likely make themselves aware of the proposed regulatory changes. A range of awareness activities will be undertaken by the Department for consumers, health professionals and suppliers. Additional awareness activities/communications specific to medical practitioners will also be undertaken/distributed by Cancer Australia (engaged by the Department) prior to and post the scheduling change.

TGA pre-implementation awareness activities include:

- § consultation on interim scheduling decision open from 23 September – 6 November 2020
- § publication of individual information sheets targeted at consumers, doctors and pharmacists on 23 September 2020<sup>159, 160</sup>
- § three webinar information sessions; two for consumers and health professionals and a third session for suppliers (all to take place in early October 2020)
- § question and answer webpage (posted on 23 September 2020).<sup>161</sup>

The time impost of all pre-implementation awareness activities has been excluded from the regulatory costing.

Following the publication of the final scheduling decision (expected mid to late December 2020), additional advice will be provided by the TGA to advise consumers and health practitioners of what the changes to the regulation of e-cigarette nicotine means for them. The advice will include clarification on how users can obtain e-cigarette nicotine and how doctors can prescribe and supply

<sup>158</sup> Development of material and coordination activities undertaken by Departmental staff are excluded from the regulatory costing.

<sup>159</sup> <<https://www.tga.gov.au/nicotine-scheduling>>.

<sup>160</sup> The TGA has already published guidance on their website regarding requirements for becoming an Authorised Prescriber for what is e-cigarette nicotine.

<sup>161</sup> <<https://www.tga.gov.au/questions-and-answers-proposed-changes-way-nicotine-supplied>>.

the same. Cancer Australia will also provide targeted communications for health practitioners following the final scheduling decision of the delegate.

Following the regulatory changes, new market opportunities are likely to emerge for the importation and domestic wholesale of e-cigarette nicotine in Australia. Thus, there may be a range of existing medical importers/wholesalers who may be future domestic wholesalers/importers and will therefore need to acquaint themselves with the regulatory changes (including state/territory requirements for the holding of a Schedule 4 licence and/or a Tobacco Retailer Licence).<sup>162</sup>

Although pharmacists may become aware of the regulatory changes to e-cigarette nicotine (for ordering and supply purposes), there will be no variation to the current requirements for the supply of a prescription medicine (i.e. e-cigarette nicotine will be filled as per the script instructions provided by the doctor).<sup>163</sup> As new therapeutic goods constantly become available within Australia (changing market and rate of innovation), this process forms part of business-as-usual activities for pharmacists. Thus, awareness activities for this population have been excluded from the regulatory costing.

## **Determination of Current Population**

As e-cigarette nicotine can currently be imported without a prescription, there is no 'current' population that has previously fulfilled regulatory requirements that need to be considered when determining the regulatory costing. As such, all proposed regulatory requirements will essentially be 'new' – hence we consider only the 'future' population in the regulatory costing.

## **Future population considerations (awareness)**

To appropriately determine the future population, modelling of the current population is required. In order to determine the current population, various data sources were sought. Noetic utilised various national surveys, research papers and data from the ABS and the Department of Health to quantify the populations impacted.

## **E-cigarette user awareness**

The largest drug use survey in Australia is the periodic National Drug Strategy Household Survey administered by the Australian Institute of Health and Welfare (AIHW). The two most recent surveys were conducted in 2016 (n=23,772) and 2019 (n=22,274). The 2019 survey noted that between 2016 and 2019 the proportion of the population who had 'ever'

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<sup>162</sup> It is noted that a large portion of potential domestic wholesalers/importers will likely utilise the services of customs brokers when undertaking various importation activities (including import permits and import declarations).

<sup>163</sup> It is noted that there are differentiations in state and territory legislation that may require a retailer to obtain a 'tobacco retail licence'. From a regulatory costing perspective, the decision to obtain said licence would be considered a business decision for a pharmacist as the regulatory changes do not force them to do so (i.e. they simply will not stock the products).

used e-cigarettes<sup>164</sup> rose from 8.8% to 11.3%, with the percentage of ‘current’<sup>165</sup> use rising from 1.2% to 2.5% (so effectively doubling).<sup>166</sup> The ABS has estimated that the resident population of Australia 14 years-old and above in June 2019 was 20,915,643<sup>167</sup>, 2.5% of this figure is 523,000 (rounded). It is considered that the e-cigarette users most likely to be impacted by these regulatory changes (initially from an awareness perspective) are those who use e-cigarettes at least monthly (highlighted row in Table 3). As ‘current’ use, as defined by AIHW, includes ‘less than monthly’ (4.4%) we need to exclude this from the current total (4.4/22.3 (17.9 [at least monthly] + 4.4 [less than monthly]) = 19.7%) so a carry forward figure of 80.3% rounded to 80%. Therefore, awareness population is 418,000 (rounded) (523,000 x 80%).

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<sup>164</sup> The National Drug Strategy Household Survey did not differentiate between e-cigarettes containing nicotine and those not containing nicotine. Noting that the survey looked at household use of tobacco, alcohol and illicit drugs, Noetic has assumed that the majority of respondents would NOT have equated non-nicotine vaping with the use of tobacco and hence e-cigarettes. It is possible that the overall e-cigarette nicotine user population has been slightly inflated by the inclusion of non-nicotine e-cigarette users in the survey data but Noetic does not feel that that this is material to the overall regulatory costing.

<sup>165</sup> Includes people who reported smoking electronic cigarettes daily, weekly, monthly or less than monthly.

<sup>166</sup> Australian Institute of Health and Welfare 2020. National Drug Strategy Household Survey 2019, p.9.

<sup>167</sup> Australian Bureau of Statistics, National, state and territory population, Released 24 September 2020, Table 8: Estimated resident population, by age and sex—at 30 June 2019, <<https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2020>>.

**Table 3. Frequency of e-cigarette use by gender, people aged 14 and over (% of e-cigarette use population)**

	Proportion					
	Males		Females		Persons	
Age group (years)	2016	2019	2016	2019	2016	2019
Daily	7.4	11.3	3.6	7.0	5.8	9.4
At least weekly (but not daily)	3.2	5.3	2.2	5.0	2.9	5.1
At least monthly (but not weekly)	1.4	3.4	2.0	3.3	1.6	3.4
<i>At least monthly</i>	<i>12.0</i>	<i>19.9</i>	<i>7.8</i>	<i>15.3</i>	<i>10.3</i>	<i>17.9</i>
Less than monthly	4.0	4.4	2.7	4.1	3.4	4.4
I used to use them, but no longer use	19.1	19.2	16.5	16.9	18.0	18.1
I only tried them once or twice	64.9	56.5	73.0	63.7	68.3	59.6

Source: Australian Institute of Health and Welfare 2020. National Drug Strategy Household Survey 2019, Table 2.21: Frequency of electronic cigarette use by gender, people aged 14 and over who have used an electronic cigarette in their lifetime, 2016 to 2019 (per cent) (refer to original data for details of sampling limitations)

Due to the fact that a significant portion of awareness material is presently available, and that general communication regarding e-cigarettes will likely be published and or accessed through various media outlets (including social media) and e-cigarette retailer websites with which the user may have an account (and thus receive communication emails from the retailer regarding importation<sup>168</sup>), and noting also the broad range of pre-decision awareness activities (excluded from the regulatory costing), Noetic has estimated that this general awareness will take 2 minutes per e-cigarette nicotine user.

### Health practitioners (doctors) awareness

<sup>168</sup> National Drug and Alcohol Research Centre: E-cigarette evidence summary, provided to Noetic by the Department on 25 August 2020.

In 2019, the Department of Health recorded that there were 37,472 General Practitioners (GPs) in Australia.<sup>169</sup> While it is assessed that only a percentage of GPs will become Authorised Prescribers (AP), the opportunity is open to all. Therefore, all GPs should make themselves aware of the proposed changes so that they can either further acquaint themselves with the process requirements for becoming an AP or so that they can advise/refer users to an AP who can prescribe them e-cigarette nicotine. It is estimated that this general awareness will take 2 minutes per GP.<sup>170</sup>

### **Potential domestic wholesalers/importers awareness**

As a result of the proposed change in regulations, new market opportunities are likely to emerge for the importation and domestic wholesale of e-cigarette nicotine in Australia. That is, as domestic sale will no longer be prohibited, importers/wholesalers will now be able to supply e-cigarette nicotine to pharmacies and potentially undercut online retailers to establish and maintain market share. Thus, there may be a range of existing medical wholesalers/importers who are potential domestic wholesalers/importers and will need to acquaint themselves with the proposed regulatory change to determine if entering the domestic e-cigarette nicotine market would be a sound business decision.<sup>171</sup> A range of information and guidance is already published on the TGA website in relation to nicotine. Therefore, it is estimated that the awareness time for each potential domestic wholesaler/importer is 5 minutes. Based off information provided by the TGA to Noetic on 7 October 2020, which related to the number of registrations for the supplier webinar information session, it is estimated that the population who will read the awareness material is 50.

## **Regulatory costing**

### *Key assumptions*

- § Only post-implementation awareness information will be in-scope for the regulatory costing
- § The time spent by the TGA and Cancer Australia in producing awareness material/ undertaking awareness activities will not be considered in the regulatory costing<sup>172</sup>

### **Inputs**

- § Number of e-cigarette nicotine users to read awareness material = 418,000
- § Time spent by e-cigarette nicotine users to read awareness material = 2 minutes
- § Number of doctors to read awareness material (general) = 37,472
- § Time spent by doctors to read awareness material (general) = 2 minutes
- § Number of potential domestic wholesalers/importers to read awareness material = 50

<sup>169</sup> <https://hwd.health.gov.au/CalendarYear.html>.

<sup>170</sup> This estimated time came from doctors reading Accessing e-cigarettes containing liquid nicotine on the TGA website – <https://www.tga.gov.au/accessing-e-cigarettes-containing-liquid-nicotine>.

<sup>171</sup> It is noted that current domestic retailers of tobacco products may also become aware of the regulatory changes as it is in their personal business interest. As this is not a requirement/regulatory responsibility it has been excluded from the costing.

<sup>172</sup> Under the OBPR Regulatory Burden Measurement Framework, government activities are not included in a regulatory costing.

§ Time spent by potential wholesalers/importers to read awareness material = 5 minutes

### *Future population (users, doctors and wholesalers/importers)*

*Step 1. Calculate total time in minutes to fulfil regulatory requirement:*

- § User awareness: user population that will read awareness material (418,000) x time in minutes required for e-cigarette nicotine users to undertake awareness activities (2 minutes) = 836,000 minutes
- § GP awareness (general): GP population that will read awareness material (general) (37,472) x time in minutes required for health practitioners to undertake awareness activities (2 minutes) = 74,944 minutes
- § Wholesaler/importer awareness: wholesaler/importer population that will read awareness material (50) x time in minutes required for potential domestic wholesalers/importers to undertake awareness activities (5 minutes) = 250 minutes

*Step 2. Calculate total time in hours to fulfil regulatory requirement*

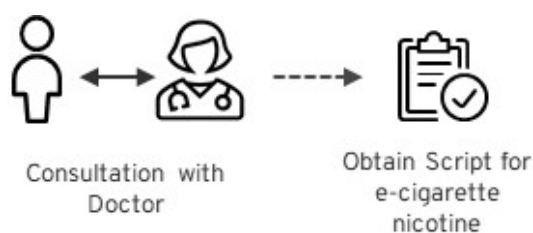
- § Users:  $836,000 / 60 = 13,933$  hours
- § GP:  $74,944 / 60 = 1,249$  hours
- § Wholesaler/importer:  $250 / 60 = 4$  hours

*Step 3. Apply the hourly rate to determine overall regulatory compliance cost:*

- §  $13,933$  hours x hourly rate (\$32.00) = \$445,867
- §  $1,249$  hours x hourly rate (\$147.46) = \$184,187
- §  $4$  hours x hourly rate (\$72.25) = \$301
- § **Total cost for user, doctor, and wholesaler/importer awareness**  
= (\$445,867 + \$184,187 + \$301) = \$630,355<sup>173</sup>

## Doctor consultation

### Overview



To obtain e-cigarette nicotine under the proposed regulatory changes (Options 3 and 4), patients who wish to use e-cigarette nicotine **for therapeutic use** must attend a consultation with a doctor (domestically). The purpose of these consultation is to ensure that the use of e-cigarette nicotine as a second-line measure to aid smoking cessation is supervised by a doctor. A likely outcome from the consultation is that patients obtain a

<sup>173</sup> All figures throughout the Report have been rounded, which may result in some minor discrepancies. All figures (including decimals) have been appropriately calculated in the costing tool.

script for e-cigarette nicotine. As there are currently no nicotine prescription products entered on the ARTG patients will need to consult with an AP (or a doctor who is willing to prescribe e-cigarette nicotine for a patient to import under the Personal Importation Scheme [online international retailer] or under the SAS B scheme).<sup>174</sup> It is noted that there are additional requirements for the AP scheme but these have been costed separately (see section of this report titled ‘AP/SAS B Scheme’). As becoming an AP is not mandatory, not all GPs will become APs. If an e-cigarette nicotine user goes to a doctor who is not an AP, the doctor can prescribe under the SAS B Scheme, prescribe for importation under the Personal Importation Scheme, or alternatively refer the patient to another doctor in their network who is an AP.

For the use of e-cigarette nicotine to be therapeutic, it must be employed as an aid for smoking cessation. It is noted that e-cigarette nicotine is not the only smoking cessation aid available to patients, and thus an alternative product (such as nicotine patches) may also be recommended by doctors.

## Prescribing behaviour by GPs

The TGA has advised Noetic that there is a low likelihood of e-cigarette nicotine being included on the Pharmaceutical Benefits Scheme (PBS) Schedule due to concerns regarding its effectiveness for cessation and cost effectiveness<sup>175</sup>, hence it will be supplied over the duration of the regulatory costing as a ‘private prescription’. Therefore, there is no specified maximum number of repeats (as recommended by the Pharmaceutical Benefits Advisory Committee (PBAC)), nor is there a specified maximum quantity that can be prescribed at any one time (hence GPs may prescribe a range of nicotine concentrations (higher potency) to cater for variance in addiction levels). However, it is considered that the general prescribing conditions as for the PBS will be applied by GPs, that is, each prescription will provide approximately one month’s therapy, which may be repeated to provide 6 months’ therapy in total.<sup>176</sup> It is also assumed that the general restriction of prescriptions remain valid for a maximum of 12 months from the date of prescribing will apply<sup>177</sup> and that this forms the upper time limit for the supply of e-cigarette nicotine from a single GP consultation.<sup>178</sup>

In terms of medicine administrative schedules, this will be up to the discretion of the doctor prescribing. If a doctor feels the risks with using e-cigarette nicotine are lower than

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<sup>174</sup> Advice from the TGA to Noetic on 14 September 2020 states that the average time for a new product to be entered on the ARTG, from date of application receipt to date of entering, is one year.

<sup>175</sup> Advice from the TGA to Noetic on 21 October 2020 stated that although some future importers/wholesalers/sponsors may wish for e-cigarette nicotine to be included on the PBS, there is a high possibility that applications could be rejected.

<sup>176</sup> It is assumed that the PBS ‘Drugs of addiction’, guidelines will not apply for e-cigarette nicotine. Department of Health, ‘The Pharmaceutical Benefits Scheme: 2. Prescribing Medicines – Information for PBS Prescribers, viewed 18 September 2020, <[https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section\\_1\\_2\\_Explanatory\\_Notes](https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes)>.

<sup>177</sup> It is assumed that States/Territories will not separately limit the maximum validity period for a prescription to 6 months. Services Australia, ‘Education Guide – Dispensing checklist for community pharmacies’, viewed 18 September 2020, <<https://www.servicesaustralia.gov.au/organisations/health-professionals/topics/education-guide-dispensing-checklist-community-pharmacies/33056>>.

<sup>178</sup> This time limit applies to both Pharmaceutical Benefits Scheme and private scripts.



smoking cigarettes, they may prescribe for a longer period (multiple repeats). Other doctors might only prescribe e-cigarette nicotine over shorter periods and schedule more frequent consultations to monitor progress towards the objective of smoking cessation.

Although under a private prescription a GP could potentially provide up to 11 monthly repeats (that is, a 12 month supply) and GPs may also choose to provide a lesser number of repeats than 5 (e.g. limit the prescription to a three-month supply (i.e. the initial prescription and two repeats)) to cater for more frequent monitoring of their patient's progress towards smoking cessation; it is assumed that on average, GPs will provide six-months' supply of e-cigarette nicotine per consultation.

## Types of GP consultations

As noted above, there are 3 options when trying to obtain a prescription for e-cigarette nicotine:

- § consultation with a doctor who is willing to prescribe e-cigarette nicotine under the AP scheme
- § consultation with a doctor who is willing to prescribe e-cigarette nicotine for a patient to import from an online retailer under the Personal Importation Scheme
- § consultation with a doctor who is willing to prescribe e-cigarette nicotine under the SAS B scheme.

There has been a recent uptake of virtual consultations through phone or video call (due to the COVID-19 pandemic).<sup>179</sup> This has increased the uptake of telehealth, which even before COVID-19 was increasingly being used in rural and regional Australia to provide primary health care.<sup>180</sup> These consultations reduce travel and wait times, as patients can go about their daily activities while they wait for the doctor to call them during the booked time period. Regardless of COVID-19 restrictions, the overall number of virtual consultations are likely to continue to increase over the 10-year period considered for the regulatory costing. Some doctors may be willing to prescribe e-cigarette nicotine through a virtual (telehealth) consultation and will send the script direct to the pharmacist (through fax or providing an electronic script<sup>181</sup>); however, other doctors may choose to see patients in-person before prescribing e-cigarette nicotine.

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<sup>179</sup> From 13 March 2020, a range of temporary Medicare Benefits Scheme (MBS) telehealth items were made available to help reduce the risk of community transmission of COVID-19 and provide protection for patients and health care providers. Specifically videoconference services could be provided as a substitute for face-to-face consultations. Department of Health, 'MBS changes factsheet': COVID-19 Temporary MSB Telehealth Services', dated 20 July 2020, viewed 18 September 2020, <

<http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Factsheet-TempBB>>.

<sup>180</sup> Stephanie Dalzell, ABC News, 'Are all doctors offering telehealth during the coronavirus pandemic and do you have to use it?', 30 March 2020, viewed 18 September 2020, <  
<https://www.abc.net.au/news/2020-03-30/what-is-telehealth-explainer-coronavirus-covid-19/12101316>>.

<sup>181</sup> Noting that electronic scripts are currently only available for defined Communities of Interest – <https://www.digitalhealth.gov.au/get-started-with-digital-health/electronic-prescriptions>.

Accenture's 2019 Digital Health Consumer Survey<sup>182</sup> Australia Results (n=1,036) assessed individual's attitudes toward traditional and non-traditional healthcare service delivery. Forty-five per cent (45%) of respondents indicated that they would be more likely to choose a medical provider if they could communicate with them through video conferencing, compared with 27% in 2016. Additionally, 74% of respondents indicated that they would be more likely to choose a medical provider if they could request prescriptions refills electronically. Twenty-one per cent (21%) of respondents say that they have used some form of virtual care, which is an increase from 12% in 2018.<sup>183</sup> Additionally, the late Dr. Harry Nespolon, former president of the Royal Australian College of General Practitioners, said the number of consultations that could be done appropriately over telehealth was about 40% and that he wanted to see the expanded telehealth services become a permanent part of the Medicare system.<sup>184</sup> Based on this data, Noetic has estimated that 20% of the initial additional GP visits for all regulatory costing options will be through a virtual consultation and that this has a yearly growth rate of 10% due to the trend of virtual consultations increasing in popularity. The remaining 80% of additional GP visits will initially likely proceed down a 'traditional' physical GP visit pathway.

Noting the above, the below consultation options have been identified for all regulatory change options.

§ **Option A:** In-person consultation

§ **Option B:** Virtual consultation.

## Activity elements of GP consultations

The following paragraphs detail the estimated timings for each of the separate activities required for a GP consultation.

### *Location of a prescribing GP*

Patients can obtain e-cigarette nicotine only if prescribed by a doctor. While not all doctors will be willing to prescribe e-cigarette nicotine (and considering that there will likely be no restrictions on the advertising of e-cigarette nicotine prescribing services for GP clinics), it is possible that GPs who are willing to prescribe e-cigarette nicotine will advertise this service online (as part of the general services the GP clinic provides). As such, to reduce time spent in consultations with doctors who are unwilling to prescribe e-cigarette nicotine, it is likely that all users will perform an initial online search for prescribing GPs in the first year of the regulatory changes coming into effect.

As detailed below (see section 'Sponsors register e-cigarette nicotine on the ARTG'), it is likely that after the first year of the regulatory changes coming into effect, e-cigarette nicotine will be registered on the ARTG. As such, users will be able to obtain a prescription

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<sup>182</sup> Accenture, 'Today's Consumer Reveal the Future of Healthcare: Accenture 2019 Digital Health Consumer Survey – Australia Results', viewed 18 September 2020, <  
[https://www.accenture.com/\\_acnmedia/PDF-99/Accenture-2019-Digital-Health-Consumer-Survey-AU.pdf](https://www.accenture.com/_acnmedia/PDF-99/Accenture-2019-Digital-Health-Consumer-Survey-AU.pdf)>.

<sup>183</sup> [https://www.accenture.com/\\_acnmedia/PDF-99/Accenture-2019-Digital-Health-Consumer-Survey-AU.pdf](https://www.accenture.com/_acnmedia/PDF-99/Accenture-2019-Digital-Health-Consumer-Survey-AU.pdf).

<sup>184</sup> <https://www.abc.net.au/news/2020-05-05/move-to-telehealth-is-here-to-stay-after-coronavirus/12212680>.

from any GP regardless of whether they are an AP, and without the need to obtain the product via the SAS B Scheme. That is, users will not be required to perform an online search for prescribing GPs after the first year as ARTG inclusion will accommodate prescribing of e-cigarette nicotine by all Australian GPs.

The time required for this online search in Year 1 is assessed to be 2 minutes, and this activity has been costed separately to Option A and Option B to account for variance in populations.

*Time to book doctor's consultation (applicable for both options)*

For both options, a patient must book a consultation. The time taken to book a consultation is estimated to be 2 minutes and this is usually completed over the phone or through an internet booking portal.

*Time to travel to the doctors/pharmacy (applicable for Option A only)*

After a consultation is booked, if a patient is attending an in-person consultation (Option A), they will need to travel to and from their consultation. As there are many variables in how someone can travel to the doctor (walk, bus, drive themselves, ride share etc.), the cost (\$) of the travel has not been included in the regulatory costing. It is estimated that, on average, patients will require 15 minutes (each way) to travel to their local doctor (therefore a total of 30 minutes).

Patients who attend a virtual consultation (Option B) will not have to spend any time travelling as they can have the virtual consultation from any location (i.e. at home or work).

*Wait times (applicable for Option A only)*

When a patient attends an in-person consultation (Option A) they will often be required to wait to see a doctor. It is estimated, based on consumer behaviour survey data<sup>185</sup>, that individuals will spend an average of 30 minutes in a waiting room before being able to see their doctor. A patient who attends a virtual consultation (Option B) will not have to spend any time waiting as they can go about their daily activities while they wait for the doctor to call them.

*Doctor consultation time (applicable for both options)*

For both options, it is assessed that the consultation activity will take the same time, as regardless of the option of consultation, the doctor and patient will need to discuss the severity of addiction, various cessation options and write a script (either paper or electronic). It is noted that if a doctor is an AP, they will also be required to provide the patient a copy of their AP authorisation for domestic prescription fulfillment. The average doctor's consultation time in Australia has been estimated to be 15 minutes per consultation.

For those who initially add a discussion regarding e-cigarette nicotine and smoking cessation onto an existing consult (i.e. one that they were already planning on attending for other health matters), it is assumed that an additional 5 minutes will be added to the

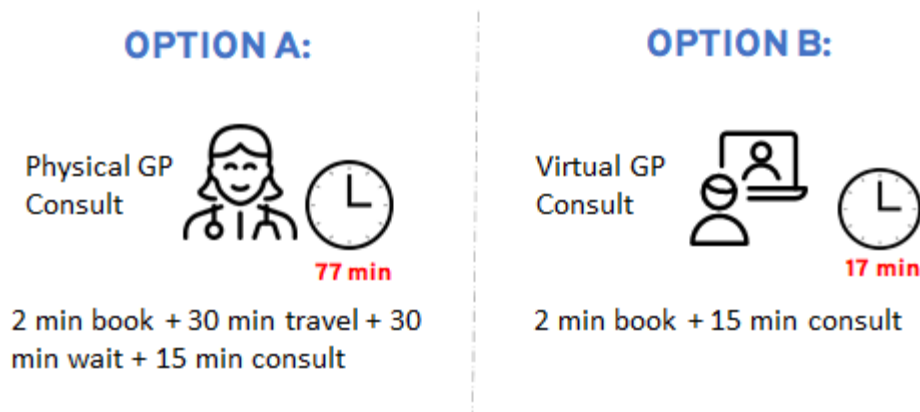
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<sup>185</sup> [www.wsmi.org/wp-content/uploads/2015/06/CONSUMER-BEHAVIOUR-FACT-BOOK\\_MARCH-2015.pdf](http://www.wsmi.org/wp-content/uploads/2015/06/CONSUMER-BEHAVIOUR-FACT-BOOK_MARCH-2015.pdf).

consultation time.<sup>186</sup> This additional five minutes will apply to the initial consult only as subsequent e-cigarette nicotine discussions with their GP (likely relating to obtaining a new prescription) will be incorporated into a standard 15 minute consult that they would have been attending for other health matters.

Figure 2 details the carry forward time for each additional GP visit (detailed in the following section).

**Figure 2. Consultation options and associated timings (excluding initial time to search for an AP – once only)**



### Additional GP visits for patients

The 'Current'<sup>187</sup> reported use of e-cigarettes (2019) is detailed in the table below. As the AIHW has included in their definition of 'Current' users survey respondents who reported use of e-cigarettes 'less than monthly' - which we have earlier excluded from our current population calculation (Table 3) in relation to awareness activities - these figures need to be adjusted. As per Table 3, the percentage of e-cigarette users who reported e-cigarette use 'at least monthly' was 17.9%, which included the 3.4% per cent who reported e-cigarette use of 'At least monthly (but not weekly)', while those who had reported using e-cigarettes 'less than monthly' was 4.4%, therefore a combined percentage of 22.3% of the e-cigarette use population were classified as 'Current' users.

Upon implementation of the proposed regulatory changes to nicotine, it is likely that there will be an element of the existing e-cigarette nicotine user population that may no longer use e-cigarettes containing nicotine due to the increased effort required to legally obtain this product (that is, the requirement to obtain a prescription for use of e-cigarette nicotine as a smoking cessation aid). Noetic has considered that an almost immediate drop-off (that is, in the first year of the proposed regulatory changes<sup>188</sup>) will be those who reported using e-cigarettes as 'less than monthly' and 'at least monthly (but not weekly' (i.e. the carry forward population will consist of daily or weekly use)). Those who reported

<sup>186</sup> Therefore remain within the parameters for a Level B GP consult (Medicare Benefits Schedule – Item 23) lasting less than 20 minutes rather than a Level C GP consult (Medicare Benefits Schedule – Item 36) lasting at least 20 and less than 40 minutes (when the Level D GP consult applies).

<sup>187</sup> Includes people who reported smoking electronic cigarettes daily, weekly, monthly or less than monthly.

<sup>188</sup> Note this population calculation excludes the education/additional support only option (Option 2).

less than weekly use of e-cigarettes is 35% ((3.4 [at least monthly but not weekly] + 4.4 [less than monthly]) = 7.8/22.3 \* 100/1). Therefore, the carry forward figure is 65% (100 - 35).

Tables 4 and 6 detail two ABS population datasets – one relating to the resident population (Table 4) – which was used for the initial awareness population calculation - and the other relating to GP visits (Table 6). Although there is approximately a 3% difference between the adjusted counts (Table 4 – 344,197) and Table 5 – 333,087), Noetic has not considered this statistically significant and will therefore use the ABS Patient Experience dataset for the calculation of additional GP visits.

**Table 4. Current use of e-cigarettes 2019 (ABS Population Statistics)**

AIHW Age Bracket #	ABS Age Brackets *	Total Persons *	Sum Age Bracket *	% Persons 'Current Use' #	Initial Count	Adjusted Count (65%)
<b>15-24</b>	15-19	1,499,482				
	20-24	1,750,276	3,249,758	4.5	146,239	95,055
<b>25-35</b>	25-29	1,906,963				
	30-34	1,892,909	3,799,872	3.6	136,795	88,917
<b>35-44</b>	35-39	1,782,288				
	40-44	1,596,129	3,378,417	3	101,353	65,879
<b>45-54</b>	45-49	1,679,537				
	50-54	1,535,552	3,215,089	2.5	80,377	52,245
<b>55-64</b>	55-59	1,547,551				
	60-64	1,391,304	2,938,855	1.6	47,022	30,564
<b>65-74</b>	65-69	1,227,097				
	70-74	1,058,030	2,285,127	0.7	15,996	10,397
<b>75+</b>	75-79	734,334				
	80-84	505,087				
	85-89	313,855				
	90-94	152,992				

95-99	43,130				
100 and over	4,992	1,754,390	<0.1	1,754	1,140
<b>Total</b>	<b>20,621,508</b>	<b>20,621,508</b>		<b>529,536</b>	<b>344,197</b>
<b>% of total population 15+</b>				<b>2.57%</b>	<b>1.67%</b>

Sources:

# = Australian Institute of Health and Welfare 2020. National Drug Strategy Household Survey 2019, Table 2.24: Current use(a) of electronic cigarettes (e-cigarettes), by age and smoker status, 2016 to 2019 (per cent) (refer to original data for details of sampling limitations)

\* = Australian Bureau of Statistics, National, state and territory population, Released 24 September 2020, Table 8: Estimated resident population, by age and sex—at 30 June 2019, <<https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2020>>.

**Table 5. Current use of e-cigarettes 2019 (ABS Patient Experiences Statistics)**

ABS Age Bracket	% Persons 'Current Use' #	Total Persons *	Initial Count	Adjusted Count (65%)
<b>Persons</b>				
<b>15-24</b>	4.5	3,111,400	140,013	91,008
<b>25-34</b>	3.6	3,658,400	131,702	85,606
<b>35-44</b>	3.0	3,292,700	98,781	64,208
<b>45-54</b>	2.5	3,156,700	78,918	51,297
<b>55-64</b>	1.6	2,874,100	45,986	29,891
<b>65-74</b>	0.7	2,215,100	15,506	10,079
<b>75+</b>	<0.1	1,536,300	1,536	998
<b>Total</b>		<b>19,844,700</b>	<b>512,442</b>	<b>333,087</b>
<b>% of total population 15 +</b>			<b>2.58%</b>	<b>1.68%</b>

Sources:

# = Australian Institute of Health and Welfare 2020. National Drug Strategy Household Survey 2019, Table 2.24: Current use(a) of electronic cigarettes (e-cigarettes), by age and smoker status, 2016 to 2019 (per cent) (refer to original data for details of sampling limitations)

\* = Source: Australian Bureau of Statistics, 48390D0002\_201819 Patient Experiences in Australia: Summary of Findings, 2018–19, Table 5.1 Persons 15 years and over, Experience of GP services in the last 12 months by age and sex: Estimate

To determine the number of additional GP visits that the proposed regulatory changes may produce, we have matched ABS data on the number of GP visits in 2018/19 against the age brackets from the AIHW data on 'current' use of e-cigarettes. We have assumed that the frequency of e-cigarette user visits to GPs is consistent with the rest of the

population within their age bracket (i.e. approximately one-third of 15-24 year-olds e-cigarette users will not visit a GP within a given year, while almost 100% of 75-84 year-olds e-cigarette users will visit a GP within a given year).

As detailed earlier in the report [see report section titled ‘Prescribing behaviour by GPs’], we have considered that an average number of GP visits required to obtain e-cigarette nicotine via a prescription is two visits per year. It is noted that patients may book a consultation exclusively for the purpose of obtaining a script for e-cigarette nicotine, or they may incorporate a discussion regarding the use of this product as a smoking cessation aid into a regular consultation. If incorporated into a GP consultation that would have been held regardless of the proposed regulatory changes, we have assessed that this will not increase the duration of a standard 15-minute GP consultation. Therefore, we have excluded from the count the proportion of the population for each age bracket that report visiting the GP two or more times per year. For those who are currently not visiting the GP at all we have factored in two additional visits and for those who are visiting the GP once per year we have factored in one additional visit. These calculations are detailed in Table 6 with the carry forward figure being an additional 188,000 GP visits which represents an uplift of 1% on the total number of GP visits for 2017-18 (as reported by NPS Medicinewise).

Table 6. GP visits

Age group (years)									
	15-24	25-34	35-44	45-54	55-64	65-74	75-84	85 and over	Total
Persons ('000)									
<b>Did not need to see a GP</b>	899.70	767.30	591.40	530.00	325.50	141.40	32.00	7.10	3,294.40
<b>Needed to but did not see a GP at all</b>	19.40	24.90	25.40	24.40	11.80	4.60	2.70	2.90	116.10
<b>Sub-total (did not see a GP)</b>	919.10	792.20	616.80	554.40	337.30	146.00	34.70	10.00	3,410.5
<b>Needed to and saw a GP</b>	2,192.30	2,866.20	2,675.90	2,602.30	2,536.80	2,069.10	1,151.10	340.50	16,434.20
<b>Total persons (A)</b>	3,111.40	3,658.40	3,292.70	3,156.70	2,874.10	2,215.10	1,185.80	350.50	19,844.70
Number of GP visits ('000)									
<b>One</b>	391.10	557.70	513.30	503.10	330.50	174.50	51.30	9.30	2,530.80
<b>Two to three</b>	923.60	1,113.70	1,138.00	1,036.40	984.90	671.30	265.40	59.60	6,192.90
<b>Four to 11</b>	733.30	964.50	818.10	802.10	885.80	897.80	561.00	161.80	5,824.40
<b>12 or more</b>	144.30	230.30	206.50	260.70	335.60	325.50	273.40	109.80	1,886.10
GP visits summary ('000)									
<b>No GP visits</b>	919.10	792.20	616.80	554.40	337.30	146.00	34.70	10.00	3,410.50
<b>% of total persons (0 visits) (B)</b>	29.54%	21.65%	18.73%	17.56%	11.74%	6.59%	2.93%	2.85%	17.19%
<b>1 GP visit</b>	391.10	557.70	513.30	503.10	330.50	174.50	51.30	9.30	2,530.80
<b>% of total persons (1 visit) (C)</b>	12.57%	15.24%	15.59%	15.94%	11.50%	7.88%	4.33%	2.65%	12.75%



Sum two or more GP visits	1,801.20	2,308.50	2,162.60	2,099.20	2,206.30	1,894.60	1,099.80	331.20	13,903.40
% of total persons (2 or more visits)	57.89%	63.10%	65.68%	66.50%	76.76%	85.53%	92.75%	94.49%	70.06%
<b>Current e-cigarette users ('000)</b>									
Current e-cigarette users (D)	91.01	85.61	64.21	51.30	29.89	10.08		1.00	
# no GP visits (B x D)	26.88	18.54	12.03	9.01	3.51	0.66		0.03	
# no GP visits x 2	53.77	37.07	24.06	18.02	7.02	1.33		0.06	
# 1 GP visit (C x D)	11.44	13.05	10.01	8.18	3.44	0.79		0.04	
Total additional GP visits	65.21	50.12	34.06	26.19	10.45	2.12		0.10	188.27
<b>Sum additional GP visits ('000)</b>									188
<b>% increase in total GP visits for 2017/18 (n=13,801,039)<sup>189</sup></b>									1.36%

Source: Australian Bureau of Statistics, 48390D0002\_201819 Patient Experiences in Australia: Summary of Findings, 2018–19, Table 5.1 Persons 15 years and over, Experience of GP services in the last 12 months by age and sex: Estimate

As identified earlier in this section, Noetic has estimated that 20% of the additional GP visits for all regulatory costing options will be through a virtual consultation and that this has a yearly growth rate of 10% due to the trend of virtual consultations increasing in popularity. The remaining 80% of additional GP visits will initially likely proceed down a 'traditional' physical GP visit pathway.

<sup>189</sup> NPS Medicinewise, 'MedicineInsight: General practice insights report July 2017 – June 2018', p.23.

## Future population considerations (GP consultations)

As the scheduling option is costed over a 10-year period, population changes need to be considered. It is likely that the proposed regulatory changes will result in various behavioural changes among existing e-cigarette users including the cessation of e-cigarette nicotine use, or a transition to alternative products. We have assumed that the overall use of e-cigarettes as a percentage of the total Australian population will decrease over the 10-year period. This is due in part to incidences of successful smoking (and thus e-cigarette) cessation attempts and increased consumer awareness of the health risks of e-cigarette nicotine use. As the future population of e-cigarette users will not likely be greater than any potential increase in new users as the population changes (overall growth as well as individuals progressing through age brackets), there is no need to adjust the base figure of e-cigarette use to account for population growth. Due to the drivers mentioned above, we are applying a reduction figure of 10% per year (for Years 2 – 10 of the regulatory costing).

The adjusted population (identified earlier in the report) will be carried forward for the first year of the regulatory costing. Following this year, a 10% reduction will be applied to the population. Based on the data referenced in Option 2 regarding virtual consultation trends, Noetic has estimated that initially (Year 1) 20% of the additional GP visits for all regulatory costing options will be through a virtual consultation and that this has a yearly growth rate of 10% due to the trend of virtual consultations increasing in popularity (see the Table below).

**Table 7. GP consultation calculations**

Transition	Year	Product Growth	Reduction in users per year	F2F Factor	Number of F2F Consultations	Number of Virtual Consultations	Check Column
<b>Yearly Growth Factor</b>		0.9					
<b>Year 1</b>	21/22	188,000		80.00	150,400	37,600	188,000
<b>Year 2</b>	22/23	169,200	-18,800	72.00	121,824	47,376	169,200
<b>Year 3</b>	23/24	152,280	-16,920	64.80	98,677	53,603	152,280
<b>Year 4</b>	24/25	137,052	-15,228	58.32	79,929	57,123	137,052
<b>Year 5</b>	25/26	123,347	-13,705	52.49	64,742	58,605	123,347
<b>Year 6</b>	26/27	111,012	-12,335	47.24	52,441	58,571	111,012
<b>Year 7</b>	27/28	99,911	-11,101	42.52	42,477	57,434	99,911
<b>Year 8</b>	28/29	89,920	-9,991	38.26	34,407	55,513	89,920
<b>Year 9</b>	30/31	80,928	-8,992	34.44	27,869	53,059	80,928
<b>Year 10</b>	31/32	72,835	-8,093	30.99	22,574	50,261	72,835
		<b>Total Growth</b>	<b>-115,165</b>		<b>695,342</b>	<b>529,143</b>	

To quantify the number of initial visits that will require an extended GP consultation time (i.e. visits that include the patient adding a discussion around smoking cessation and the use of e-cigarette nicotine), the total number of consultations needs to be determined. To determine this number, the total population of current e-cigarette users 2019 (Table 4) was used. From this, the excluded population (i.e. those that did not need to attend an 'additional' consultation) needed to be identified. To do this, the data indicating % of total persons (2 or more visits) was used (see Table 5). As such the total number of

consultations that require an extended consultation (initial consultation only) is  $(0.706 * 333,087 = 235,159)$ .<sup>190</sup>

## Regulatory costing (GP consultations)

### *Key assumptions*

- § There is no additional regulatory burden on doctors prescribing e-cigarette nicotine to patients as the total number of patients they see each day is not likely to change
- § Only e-cigarette nicotine specific consultations are in-scope for the calculation of regulatory burden

### **Inputs**

- § Total number of initial online searches for a prescribing GP = 344,197
- § Total number of future ‘additional’ physical consultations = 695,342
- § Total number of future ‘additional’ virtual consultations 529,143
- § Total number of extended consultations required = 235,159
- § Time required for users to perform initial online search for prescribing GPs = 2 minutes
- § Time required for user to undertake physical consultation (Option A) = 77 minutes
- § Time required for user to undertake virtual consultations (Option B) = 17 minutes
- § Time required for extended consultation = 5 minutes

### *Future population (GP consultations)*

*Step 1.* Calculate total time in minutes to fulfil regulatory requirement:

- § Initial online search for prescribing GPs: number of initial online searches (344,197) x time required for search (2 minutes) = 688,394 minutes
- § Physical Consultations: Number of physical consultations (695,342) x time required for consultation (77 minutes) = 53,541,334 minutes
- § Virtual Consultation: Number of virtual consultations (529,143) x time required for consultation (17 minutes) = 8,995,431 minutes

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<sup>190</sup> This figure will capture the initial population (Year 1) of current e-cigarette nicotine users who visit a GP to obtain a prescription for e-cigarette nicotine as a smoking cessation aid. Over years 2 – 10 of the regulatory costing, new e-cigarette nicotine users will enter this population while some current e-cigarette nicotine users will exit. Many of these new e-cigarette nicotine users are likely to be in the 15-24 age bracket, who already have the lowest GP visit rate (excluding the proposed regulatory change) and so will be captured in the carry forward count for additional GP consultations. Noetic acknowledge that the extent to which new e-cigarette nicotine users over years 2 -10 of the regulatory costing are not captured in the count of additional GP consultations. This will represent an underestimation of the associated regulatory cost (by 5 minutes per instance) but Noetic do not feel that this factor is material to the overall regulatory costing.

§ Extended Consultations: Number of extended consultations required (235,159) x time required for consultation (5 minutes) = 1,175,795

§ Total minutes: Initial Online Search (688,394) + Physical Consultation (53,541,334) + Virtual Consultation (8,995,431) + Extended Consultation (1,175,795) = 64,400,954

Step 2. Calculate total time in hours to fulfil regulatory requirement:

§  $64,400,954/60 = 1,073,349$  hours

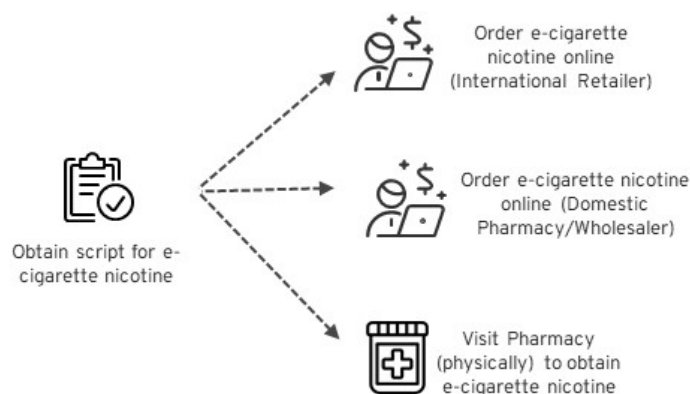
Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

**Total cost for future users to attend doctor's consultations**

**= 1,073,349 hours x \$32.00 = \$34,347,175**

## Obtaining e-cigarette nicotine

### Overview



Once a user has obtained a prescription (script) for e-cigarette nicotine, they are then required to visit a pharmacy (domestic online or in person) or an overseas retailer to obtain the product. For domestic purchase, users will be required to provide both the script and the letter of AP authorisation to the pharmacy. Likewise, the pharmacist will need to provide to an importer<sup>191</sup> of e-cigarette nicotine evidence of AP interaction for stock release. Alternatively, APs may establish a non-commercial relationship with a pharmacy, who in turn establishes a relationship with an importer of e-cigarette nicotine to expedite access to e-cigarette nicotine by providing enough stock to meet demand projections (i.e. move away from the delay inherent in script-by-script order fulfillment).

Under Scheduling, users will be able to order e-cigarette nicotine online through an international retailer (e.g. from the US, New Zealand) through the Personal Importation

<sup>191</sup> The TGA advised on 23 October 2020, that there are no special requirements under Commonwealth regulation for importers of e-cigarette nicotine products. As for any unapproved therapeutic good, the sponsor must comply with the conditions specified in Schedule 5A of the Therapeutic Goods Regulations 1990 in order to hold the unapproved good. Additional state and territory requirements may apply with respect to the warehousing of medicines (Schedule 4 licence).

Scheme (if they order no more than a 3-month supply).<sup>192</sup> Thus the user has three options for obtaining e-cigarette nicotine:

- § **Option A:** Visit physical pharmacy to obtain e-cigarette nicotine
- § **Option B:** Order e-cigarette nicotine from an online pharmacy (domestic only)
- § **Option C:** Order e-cigarette nicotine online (international retailer)

According to the *Guidelines for Dispensing of Medicines*, produced by the Pharmacy Board of Australia<sup>193</sup>, the supply of multiple quantities of a prescription at one time is permitted under the regulatory framework but this should only occur at the specific direction of the prescriber on each occasion unless exceptional circumstances exists to the satisfaction of the pharmacist. For this reason, Noetic has assumed that each pharmacy interaction will provide a 1-month supply of e-cigarette nicotine, hence up to 12 pharmacy interactions in a year (noting that a 3-month supply can be obtained via the personal importation scheme).

In terms of the additional regulatory burden associated with a physical pharmacy visit (Option A), it is noted that most GP clinics are likely to be situated in close proximity to a pharmacy, and, that outside a GP visit, many individuals are likely to incorporate a trip to the pharmacy into other personal activities (i.e. weekly grocery shop). Thus, the travel time associated with a physical pharmacy visit is estimated to be minimal (2 minutes). Noetic has estimated that a visit to a physical pharmacy would be 5 minutes, incorporating both the wait and consultation time with the pharmacist. Thus, the total time for a physical visit is 7 minutes.

There has also been a recent uptake in the use of online pharmacies (due to the COVID-19 pandemic). It is likely that these online pharmacy visits will increase in popularity over the 10-year period of the regulatory costing due to convenience and likely business improvements to online pharmacy outlets. This option provides a reduced regulatory cost timing as no travel or wait times are associated. Another reduced regulatory burden under this option, is the ability to upload a script and have it 'on file'. This means users will not need to re-upload their script when getting a repeat filled (thus users are only likely to upload a script twice a year (in line with GP consultations).

Patients who are visiting an online pharmacy (Option B) need to send their script to the online domestic pharmacy of their choice. This can be through posting the physical copy of their script by mail (free postage), the doctor providing an electronic script direct to the pharmacy, or the user uploading/sending the script to their pharmacy of choice. Once the script has been uploaded/provided (virtually or by mail) (estimated to be 4 minutes), the usual processes for online shopping are applicable. As this provides no addition to the regulatory burden (current baseline activity for obtaining e-cigarette nicotine via an online retailer) all activities outside uploading the script have been excluded from the regulatory burden costing.

Option C provides users with the opportunity to buy from a broader range of retailers, rather than being limited to the domestic market. Additionally, users will not need to provide evidence of a script from a domestic doctor (upon submitting an initial order) in

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<sup>192</sup> Department of Health – Therapeutic Goods Administration, 'Personal importation scheme', 18 March 2015, viewed 18 September 2020, < <https://www.tga.gov.au/personal-importation-scheme>>.

<sup>193</sup> Pharmacy Board of Australia, *Guidelines for Dispensing a Medicines*, September 2015.

the same way they would in a purchase from a domestic online pharmacy. Thus, this pathway most resembles the current purchasing behaviour and thus does not incur any additional time (burden).

**Figure 3. ‘Pharmacy’ visit options and associated timings**



### **Future population considerations (‘pharmacy’ visits)**

From the total number of GP consultations required (quantified under ‘doctor consultation’ (n=333,087)), it is anticipated that not all those who attend a GP consult will obtain a script for e-cigarette nicotine. Some patients may choose/be advised by their GP that a different smoking cessation pathway is preferable and therefore will not require a visit to a pharmacy to obtain e-cigarette nicotine. Thus, the total number of consultations resulting in a prescription being written for e-cigarette nicotine has been reduced by 15% ( $0.85 \times 333,087 = 283,124$ ).

As the population of users will likely be reduced following implementation of the regulatory changes (due in part to incidences of successful smoking cessation attempts and increased consumer awareness of the health risks of e-cigarette nicotine use), so too will the number of pharmacy visits in order to obtain e-cigarette nicotine. As such, Noetic has estimated that the number of users obtaining e-cigarette nicotine will see a reduction of 10% per year (detailed in tables 8, 9 and 10).

Under the proposed regulatory change, it is likely that obtaining e-cigarette nicotine online from an international retailer under Option C will be a popular option as it will result in the lowest time burden for users, and is most representative of the current obtainment pathway. As such, Noetic has estimated that 50% of users ( $0.5 \times 283,124 = 141,562$ ) will order e-cigarette nicotine online through an international retailer (and thus will not incur an additional regulatory burden).

**Table 8. Growth in online international retailer visits over the 10-year period (not costed)**

Transition	Year	Online retailer pathway growth
<b>Yearly Growth Factor</b>		0.90
<b>Data year</b>	21/22	141,562
<b>Year 2</b>	22/23	127,406
<b>Year 3</b>	23/24	114,665
<b>Year 4</b>	24/25	103,199
<b>Year 5</b>	25/26	92,879
<b>Year 6</b>	26/27	83,591
<b>Year 7</b>	27/28	75,232
<b>Year 8</b>	28/29	67,709

<b>Year 9</b>	30/31	60,938
<b>Year 10</b>	31/32	54,844
	<b>Total Growth</b>	922,025

Furthermore, Noetic has estimated that 30% of users will order e-cigarette nicotine from a future (online) domestic retailer (Option B) ( $0.3 \times 283,124 = 84,937$ ). Since the postage costs are likely to be less, there will be no international transaction fees and some users may feel more comfortable ordering from a domestic supplier. This option represents a burden of 4 minutes, due to the requirement to upload or mail a script. It is assumed that the consumer will only be required to upload their script twice a year (in line with doctor consultations (i.e. new script)), thus the remaining 10 visits to the online retailer (over the 12-month period) do not incur an additional regulatory burden. This results in an adjusted population of  $84,937 \times 2 = 169,874$ .

**Table 9. Growth in virtual domestic pharmacy visits over the 10-year period**

Transition	Year	Virtual Domestic Pharmacy visits Growth
<b>Yearly Growth Factor</b>		0.90
<b>Data year</b>	21/22	169,874
<b>Year 2</b>	22/23	152,887
<b>Year 3</b>	23/24	137,598
<b>Year 4</b>	24/25	123,838
<b>Year 5</b>	25/26	111,454
<b>Year 6</b>	26/27	100,309
<b>Year 7</b>	27/28	90,278
<b>Year 8</b>	28/29	81,250
<b>Year 9</b>	30/31	73,125
<b>Year 10</b>	31/32	65,813
	<b>Total Growth</b>	1,106,426

Noetic has estimated that the remaining 20% of users ( $0.2 \times 283,124 = 56,625$ ) will visit a pharmacy in-person to obtain e-cigarette nicotine as this is the traditional obtainment pathway for prescription medicines. For physical visits, each user will need to go to the pharmacy every month to get their e-cigarette nicotine (i.e. twelve times per year).<sup>194</sup> Thus, the total physical pharmacy visits over a 12-month period is ( $56,625 \times 12 = 679,498$ ).

The National Drug Research Institute, Curtin University report titled 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16'<sup>195</sup> identified 46 medical conditions requiring treatment and care caused by active smoking. Hence, it is likely that a portion of users seeking to obtain e-cigarette nicotine will already be visiting a pharmacy to obtain therapeutic goods related to a range of medical conditions caused by smoking. Noetic estimates that 30% of physical pharmacy visits will therefore not be undertaken

<sup>194</sup> It is noted that this figure is likely to be a moderate overestimation as pharmacists may provide more than one month's worth of e-cigarette nicotine (i.e. reducing the number of pharmacy visits required).

<sup>195</sup> National Drug Research Institute, Curtin University report titled 'Identifying the Social Costs of Tobacco Use to Australia in 2015/16', 2019, <<https://ndri.curtin.edu.au/NDRI/media/documents/publications/T273.pdf>>.

exclusively as a result of the regulatory changes, making the adjusted total number of physical pharmacy visits ( $0.7 \times 679,498 = 475,648$ ).

**Table 10. Growth in in-person pharmacy visits over the 10-year period**

Transition	Year	In-person Pharmacy visits Growth
<b>Yearly Growth Factor</b>		0.90
<b>Data year</b>	21/22	475,648
<b>Year 2</b>	22/23	428,083
<b>Year 3</b>	23/24	385,275
<b>Year 4</b>	24/25	346,748
<b>Year 5</b>	25/26	312,073
<b>Year 6</b>	26/27	280,866
<b>Year 7</b>	27/28	252,779
<b>Year 8</b>	28/29	227,501
<b>Year 9</b>	30/31	204,751
<b>Year 10</b>	31/32	184,276
	<b>Total Growth</b>	3,098,000

## Regulatory costing

### *Key assumptions*

- § There will be no change in timings required for an initial script to be dispensed and a repeat being dispensed for physical pharmacy visits
- § The same timing has been attributed to uploading a script online and physically mailing<sup>196</sup>
- § Ordering from an international retailer (50% of population) has been excluded from the regulatory burden costing as this activity resembles the current baseline requirement for obtaining e-cigarette nicotine

<sup>196</sup> It is assumed this activity will be completed alongside other personal activities such as grocery shopping as every local shopping precinct is likely to have a post box.



## Inputs

- § Number of visits under Option A (physical) = 3,098,000
- § Number of visits under Option B (virtual domestic) = 1,106,426
- § Time in minutes for Option A (physical) = 7 minutes
- § Time in minutes for Option B (physical) = 4 minutes

### *Future population (pharmacy visits)*

*Step 1.* Calculate total time in minutes to fulfil regulatory requirement:

- § Physical pharmacy (Option A): Number of physical pharmacy visits (3,098,000) x time required for visit (7 minutes) = 21,686,000 minutes
- § Virtual (domestic) pharmacy (Option B): Number of virtual pharmacy visits (1,106,426) x time required for visit (4 minutes) = 4,425,704 minutes
- § Physical pharmacy visits (21,686,000) + virtual pharmacy visits (4,425,704) = 26,111,704 minutes

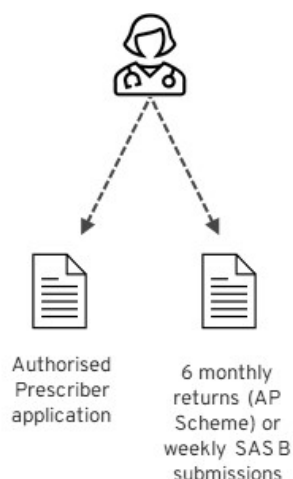
*Step 2.* Calculate total time in hours to fulfil regulatory requirement:

- §  $26,111,704/60 = 435,195$  hours

*Step 3.* Apply the hourly rate to determine overall regulatory compliance cost:

- § **Total cost for future users to attend a pharmacy = 435,195 hours x \$32.00 = \$13,926,242**

## AP/SAS B Scheme



## Overview

To be able to prescribe e-cigarette nicotine for domestic supply<sup>197</sup>, doctors must either be an AP or submit a SAS B submission.<sup>198</sup> Prior to and following implementation of the scheduling change, the TGA, along with the support of Cancer Australia will provide communication and education material noting the relative ease with which he or she may qualify for an AP authorisation as opposed to use of the SAS B pathway on a patient-by-patient : prescription-by-prescription basis. The SAS B pathway generates a significantly higher administrative burden to doctors than the AP route. There is also a delay between the doctor submitting the SAS B submission and receiving approval from the TGA, which will likely result in a patient having to collect their script from the doctor post consultation or visiting the pharmacy a few days later. This, along with the TGA encouraging use of the AP pathway, is likely to deter the majority of doctors and patients from going down the SAS B pathway. Therefore, it is estimated that only a small percentage of doctors may prefer to use the SAS B pathway.

## GPs Complete AP Application

Doctors who will choose to become APs for e-cigarette nicotine under the proposed change in regulation will be required to acquaint themselves more thoroughly with the changes and be aware of the requirements associated with becoming an AP. Those who are not already familiar with the AP process will need to do some initial reading on the AP scheme<sup>199</sup> to understand the application process and ongoing reporting requirements. The estimated reading time is 10 minutes for each doctor.<sup>200</sup>

Doctors who already have an account with a system hosted by the TGA will need to login with their username and password on the AP portal. If a doctor does not already have a login, they will be required to set up a new one including a username; password; email address; and personal information such as full name, health practitioner type, AHPRA registration number; and contact details. The estimated time for establishing an account is 5 minutes. If a doctor already has an account, they will need to log-in with their username and password. The estimated time for login with an existing account is 30 seconds.

The next step is completing and submitting an application to become an AP. For e-cigarette nicotine, the application process has been streamlined as there is no requirement, for this medicine, for the indication of smoking cessation for Human Research Ethics Committee (HREC) approval. Doctors need to complete four simple steps before reviewing and submitting the application. The estimated time for making a new AP application is 5 minutes. Each application is valid for 5 years (likely covering the entire period (+) of the regulatory change).<sup>201</sup> Considering that it is not likely that an ARTG

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<sup>197</sup> Patients who intend to obtain e-cigarette nicotine under the provisions of the Personal Importation Scheme do not require a prescription from an AP; any currently registered GP can provide the prescription.

<sup>198</sup> Note this requirement will no longer be applicable once a single e-cigarette nicotine product is entered on the ARTG.

<sup>199</sup> Such as the Authorised Prescriber user guidance document from the TGA – <https://www.tga.gov.au/publication/authorised-prescriber-user-guidance>.

<sup>200</sup> This estimated time came from doctors reading material on the TGA website such as Accessing e-cigarettes containing liquid nicotine – <https://www.tga.gov.au/accessing-e-cigarettes-containing-liquid-nicotine>, material on the Special Access Scheme page – <https://www.tga.gov.au/form/special-access-scheme>, and on the Authorised Prescribers page – <https://www.tga.gov.au/form/authorised-prescribers>.

<sup>201</sup> An AP application expires after 5 years. After this time doctors will be required to make a new AP submission for nicotine if they wish to continue prescribing under the scheme.

application will be approved in less than 1 year, it is assumed that AP will be required for the entire first year of the regulatory change.

Therefore, the total time for a doctor to become an AP is 20 minutes. Those who are already familiar with the process and have an account with the TGA will only need 5 ½ minutes to complete an application.

### **GPs Complete AP 6-monthly Reports**

A requirement under the AP scheme is that doctors must report on the number of new and existing patients who have been prescribed e-cigarette nicotine within each 6-month period (i.e. 1 January to 30 June/1 July to 31 December). The purpose of this is for the TGA to monitor the quantities of new and repeat patients prescribed e-cigarette nicotine under the proposed regulatory change.

APs can submit this information by using the online portal (the same which is used to register and submit applications). To complete a report, they will need to log-in and complete the report template provided. The reporting template is a simple one pager, which requires a doctor to provide some initial details (including name, product, approval number and time of reporting). They are then required to enter the number of new and repeat patients in the past 6-month period. APs should be able to easily access this information from their prescription software (transferable to an excel spreadsheet). There should not be any requirement for a doctor (or support medical clerk) to change their record keeping processes or update patient databases to obtain this information. The estimated time for submitting an AP 6 monthly report is 10 minutes per AP.

### **GPs Complete SAS B Applications**

Doctors who are not already familiar with the SAS B process will need to do some initial reading<sup>202</sup> to understand the submission process and ongoing requirements. The estimated reading time is 10 minutes for each doctor.

Furthermore, if a doctor does not already have a login, they will also be required to set up a new TGA hosted system account including username; password; email address; and personal information such as full name; health practitioner type; AHPRA registration number; and contact details. The estimated time for making an account is 5 minutes.

All doctors who are using the SAS B route must then make a new SAS B submission for each of their patients that they are prescribing e-cigarette nicotine to under the proposed regulatory change. They must first log-in (estimated to be 30 seconds), select 'New SAS submission', fill in the active ingredient, dosage form and indication and provide patient details (patient initials, date of birth and gender) and a diagnosis and clinical justification for the prescription. The doctor must then read a disclaimer form and submit the application to the TGA. The estimated time for each new SAS B submission is 5 minutes.

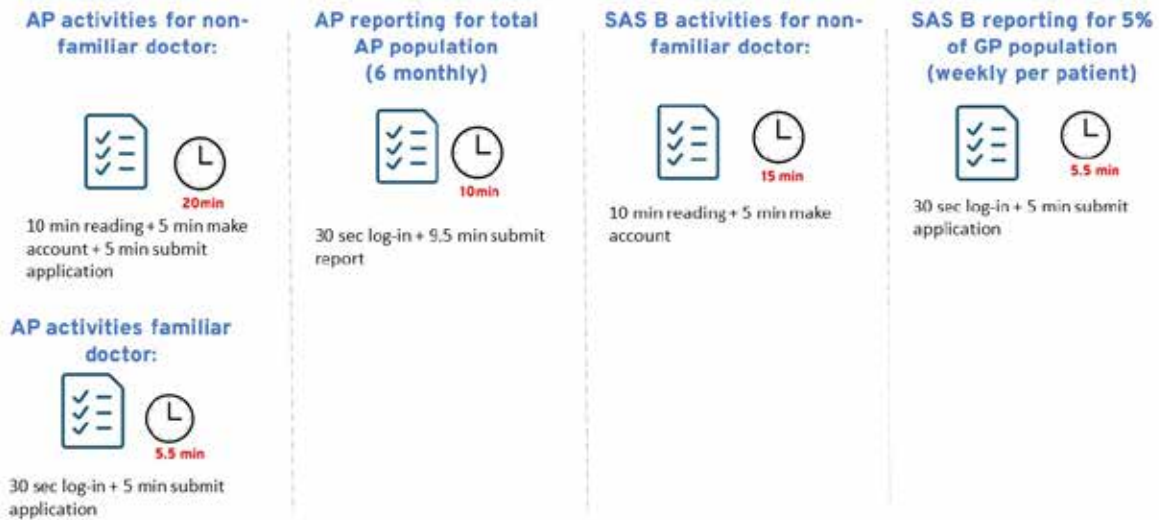
The above submission needs to be completed per patient, submitted per week.

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<sup>202</sup> Such as the SAS Online System Guidance document from the TGA – <https://www.tga.gov.au/publication/special-access-scheme-sas-online-system-guidance>.

Considering it is not likely that an ARTG application will be approved in less than 1 year, it is assumed that this specific change will have the same regulatory impact across all options (noting different implementation dates).

**Figure 4. AP/SAS B requirements and associated timings**



## Future population considerations (AP/SAS B)

### Future Population of GPs Required to Complete AP Activities

A 2018 report from the Grattan Institute states that while there is no authoritative source for the number of GP clinics in Australia, estimates generally put the number at around 7,000.<sup>203,204</sup> Noetic have estimated that, given the anecdotal evidence of some reluctance on the part of GPs to engage in prescribing e-cigarette nicotine as a smoking cessation aid (Royal Australian College of General Practitioners (RACGP) guidelines<sup>205</sup>), and the option for e-cigarette nicotine to be obtained without a prescription provided by an AP via the Personal Importation Scheme, not every GP clinic will choose to have an AP. Due to the estimation above, that 50% of users will import e-cigarette nicotine from an international retailer (under the Personal Importation Scheme), and thus do not require an AP (or SAS B) provided prescription, a similar logic has been applied to the number of APs. As such, it is estimated that only 50% of clinics will have a single AP ( $0.50 \times 7,000 = 3,500$ ).

Of the carry-forward figure of 3,500 doctors, it is assumed that 20% are not familiar with the scheme and thus require the full time allocated (20 minutes). The remaining 80% will only need to log-in and complete the AP application (5 ½ minutes).

<sup>203</sup> <https://www.racgp.org.au/getattachment/00185c4e-441b-45a6-88d1-8f05c71843cd/Supporting-smoking-cessation-A-guide-for-health-professionals.aspx>

<sup>204</sup> The Grattan Institute estimates that this figure is broken down into 3000 solo private practices and 4000 group private practices.

<sup>205</sup> <https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines>

All 3,500 APs will need to complete 6-monthly reporting (2 occurrences over the lifetime of the regulatory change) which equates to 20 minutes in total.

## Future Population of GPs Required to Complete SAS B Activities

For doctors not familiar with SAS B, read-in and initial login creation need to be costed separately. It is estimated that 5% of the total GP population (37,472) may need to do additional read in/login creation (N=1,874). The timing that is estimated for this is 15 minutes per doctor. As submissions are completed per patient prescription, it is assessed that 5% of total consultations (0.05\*(344,197\*2)) for the period of regulatory changes will require SAS B administration for doctors (5 ½ minutes per submission).

## Regulatory costing

### Inputs

- § Total population doctors likely to become an AP = 3,500
- § Percentage of the population required to become aware of the AP scheme = 20%
- § Time in minutes required for doctors to become aware of the AP scheme = 10
- § Time in minutes required for doctors to set up a new account = 5
- § Time in minutes required to prepare AP submission = 5
- § Percentage of the population required to log-in and prepare submission = 80%
- § Time in minutes required to login to account (AP and SAS B) = 0.5
- § Time in minutes required to undergo 6-monthly reporting activities = 10
- § Number of times 6-monthly reporting occurs over a 1-year period = 2
- § Total number of GPs required to become aware of SAS B scheme (0.05\*37,472 = 1,874)
- § Time in minutes required to become aware of SAS B scheme = 10
- § Time in minutes required to create a new account = 5
- § Percentage of consultations requiring SAS B administration = 5%
- § Total number of consultations (SAS B) = (0.05\*(344,197\*2)) = 34,419
- § Time in minutes required to submit SAS B form = 5

## Future Population (GPs Complete AP Activities)

*Step 1.* Calculate total time in minutes to fulfil regulatory requirement:

- § New APs with no account/awareness: number of doctors likely to become APs (n=3,500) x percentage of population required to become aware of the AP scheme (20%) (0.2\*3,500 = 700) x time in minutes required to undertake awareness activities, set up an account and prepare submission (10 + 5 + 5 = 20 minutes) = 14,000 minutes
- § New APs with existing account/awareness: number of doctors likely to become APs (n=3,500) x percentage of population required to prepare submission (80%) (0.8\*3,500 = 2,800) x time required to log-in and prepare submission (5 + 0.5 minutes) = 15,400 minutes
- § APs complete 6-monthly reporting: Number of APs (3,500) x time required for reporting (10 minutes) x number of times performed a year (2) = 70,000 minutes
- § New APs with no account complete AP activities (14,000 minutes) + New APs with existing account complete AP activities (15,400 minutes) + APs complete 6-monthly reporting activities (70,000 minutes) = 99,400 minutes

*Step 2.* Calculate total time in hours to fulfil regulatory requirement:

§  $99,400/60 = 1,657$  hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

§ **Total cost for GPs to undertake AP activities = 1,657 hours x hourly rate (\$147.46) = \$244,292**

### **Future Population (GPs Complete SAS B Activities)**

Step 1. Calculate total time in minutes to fulfil regulatory requirement:

§ New SAS B GPs: 5% of total GP population required to become aware of the SAS B scheme (1874) x total time in minutes required to become aware of SAS B scheme and create account (15 minutes) = 28,104 minutes

§ Ongoing SAS B requirements: 5% of total number of consultations requiring SAS B administration (34,420) x total time required to complete SAS B administration requirements (5.5 minutes) = 189,308 minutes

§ Time for GPs needing to become aware of requirements (28,104) + ongoing SAS B requirements (189,308) = 217,412 minutes

Step 2. Calculate total time in hours to fulfil regulatory requirement:

§  $217,412/60 = 3,624$  hours

Step 3. Apply the hourly rate to determine overall regulatory compliance cost:

§ **Total cost for GPs to undertake SAS B activities = 3,624 hours x hourly rate (\$147.46) = \$534,327**

## Child Resistant Container Closure



Under Option 3, e-cigarette nicotine containing products would have to meet Australian child proofing standards. This approach recognises the harms that are associated with nicotine as a poison and places appropriate packaging restrictions on nicotine containing e-cigarette devices.

Data provided to Noetic by the TGA<sup>206</sup> identified that the key overseas sources of e-cigarette nicotine were UK, US, New Zealand and Malaysia. The EU introduced new requirements for e-cigarette nicotine products in 2014. These were implemented by the Medicines and Healthcare products Regulatory Agency (MHRA) via the 'Tobacco and Related Products Regulation 2016', which states that an 'electronic cigarette or refill container must be – child-resistant and tamper-evident ...'<sup>207</sup>, with effect from 20 May 2017. In the US the *Child Nicotine Poisoning Prevention Act 2015* required any e-cigarette nicotine from 2016 to be sold in child-resistant packaging.<sup>208</sup> Noetic understands that NZ is proposing including child—resistant closures and tamper-evident measures for e-cigarette nicotine packaging.<sup>209</sup> Noetic was unable to determine the regulatory framework for the packaging of e-cigarette nicotine in Malaysia. We have assumed that Malaysia would likely follow a similar regulatory pathway to other major e-cigarette producers or that export product will be produced in child-resistant packaging given that their likely major export markets (UK, US, Australia etc.) will require this (less the Malaysian exporters lose market share).

As e-cigarette nicotine is not currently nor likely to be produced in Australia in the short-to-mid term, it has been assumed that domestic supply will be sourced from overseas manufacturers. The key overseas sources have, or will likely shortly move to, manufacturing e-cigarette nicotine in child-resistant packaging. Any regulatory burden arising from changes to the manufacturing of e-cigarette nicotine to accommodate child-resistant packaging rules will likely arise from fulfilling regulatory requirements in the country of manufacture and are therefore excluded from the Australian regulatory costing.

<sup>206</sup> Email TGA to Noetic dated 25 August 2020.

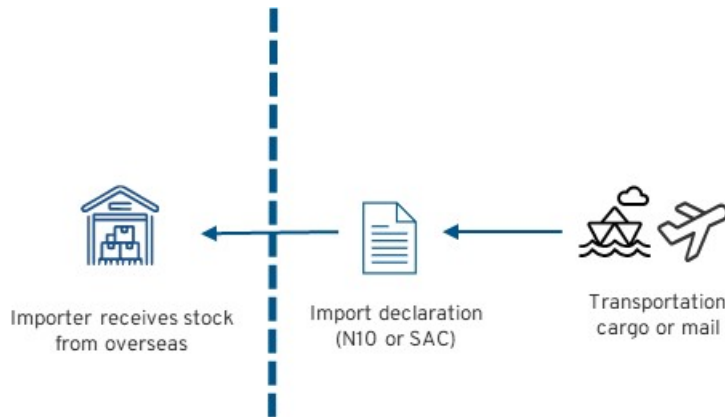
<sup>207</sup> United Kingdom, 'The Tobacco and Related Products Regulation 2016', s.36(7)(a), <<https://www.legislation.gov.uk/uksi/2016/507/contents/made>>.

<sup>208</sup> United States of America, S.142 – *Child Nicotine Poisoning Prevention Act 2015*, <<https://www.congress.gov/bill/114th-congress/senate-bill/142>>

<sup>209</sup> Email TGA to Noetic dated 23 November 2020.

## Importers Complete Import Declaration (N10 or SAC)

For e-cigarette nicotine products to legally enter Australia, it is the responsibility of the importer (or the customs broker working on their behalf) to complete an import declaration form. The import declaration is submitted to the ABF.



If the total value of an import is less than \$1000, future importers need to lodge a self-assessed clearance (SAC) declaration through either a licenced customs broker/courier or directly through the ICS. However, this activity will not be considered in the regulatory costing since it is unlikely that it would be economically viable for importers to import less than \$1000 of e-cigarette nicotine in a single consignment.

If the total value of an import is equal to or greater than \$1000, future importers, or a customs broker/courier acting on their behalf, will need to complete an import declaration form (N10) and lodge it electronically via the ICS. The N10 requires information such as contact details, valuations, transport details and tariff details to be included, along with a declaration.

As future importers of e-cigarette nicotine will likely already be involved with the importation of pharmaceuticals, it is considered that they will likely have in place business-to-business data interchange software to largely automate the production of the required importation documentation. That is, their stock management system will provide the necessary details to their customs broker/or via an API with ICS to complete the importation documentation. Thus, this activity does not represent a material burden and has not been included in the regulatory costing.

## Sponsors register e-cigarette nicotine on the ARTG

Noting that there are no commercial tobacco farms in Australia, Noetic has been advised by the TGA that it is considered unlikely that domestic production of e-cigarette nicotine will occur in the foreseeable future.<sup>210</sup> Hence, production is likely to continue to remain offshore. The absence of targeted border enforcement powers in the past has enabled the development of a major market for e-cigarette nicotine to be provided via online purchase directly to Australian consumers.

<sup>210</sup> Advice provided during a workshop on 21 September 2020, from representatives from the TGA.



The proposed regulatory change will upset the existing market dynamic and will likely create favourable market opportunities for domestic pharmacies to potentially undercut overseas retailers in both price as well as shipping times. Additionally, e-cigarette nicotine is unlikely to be entered on the PBS (see earlier comments) and there is no PBS reimbursement under the Seventh Community Pharmacy Agreement (7CPA) for dispensing of unapproved medicines. Therefore, any pricing of unapproved medicines, and medicines not listed on the PBS, are a private market matter, and any remuneration derived by parties handling such medicines is a commercial matter between the relevant parties. The Commonwealth has no price setting role<sup>211</sup>, thereby allowing early market entrants to potentially make high profits noting that due to the addictive nature of e-cigarette nicotine it has high demand inelasticity. Additionally, there is a higher likelihood of e-cigarette nicotine shipments imported under the conditions of the Personal Importation Scheme being stopped at the border (due to the non-provision of script details when ordering online from an overseas supplier). However, it is likely that the favourable market conditions will be capitalised upon by many pharmacies, inciting a fair degree of competition within the market which will stabilise prices at a reasonable level.

Registering e-cigarette nicotine on the ARTG will also potentially increase market share as all doctors (not just APs) will be able to prescribe it, thereby potentially opening up additional avenues for e-cigarette users to obtain the product. Additionally, medicines entered on the ARTG may be considered to be more ‘acceptable’ by doctors and thus more likely to be prescribed to users.

The below table provides a summary of all regulatory activities and associated timings for registering a product in the ARTG.<sup>212</sup> It is noted that the below timings have been estimated by the TGA<sup>213</sup>, and that variations to the timings are likely depending on the experience of the sponsor and the specific application details. In preparation of the table, the following assumptions have been made:

- § The table is based off of a Cat 1 Major variation in Australia via a literature-based submission
- § The table does not include the effort on the sponsors part to find and evaluate relevant literature, nor negotiating the use of any particular reference material
- § The sponsor in question has experience with the TGA and the Australian electronic Technical Document (eCTD) and has the relevant infrastructure in place to support its applications, including sufficient expertise to answer questions
- § The application is of good quality with few questions arising, that do not require significant work on behalf of the applicant to answer

<sup>211</sup> The ABF has advised Noetic on 21 September 2020 that no excise duty will be applied to nicotine, which will allow wholesalers to undercut traditional tobacco products such as cigarettes.

<sup>212</sup> The format of this table was based on an assessment of the activities (and associated time) required to list a medical device on the ARTG previously agreed by OBPR (and TGA). For the purpose of this costing, the TGA reviewed and edited the table to adjust for registering a medicine on the ARTG.

<sup>213</sup> The table, including modified timings was provided to Noetic, through email correspondence with the TGA on 1 October 2020.

**Table 11. Regulatory activities (and associated time) for listing a product in the ARTG**

Task	Subtask	Application (A)	Subtask – Time (minutes)	Remarks
		Ongoing (O)		
Create eBS Account	Become familiar with eBS Manual	A	0	Note third assumption above.
	Organisation Details Form	A	0	
	eBS Access Form	A	0	
	Wait for account creation	A	0	
Determine Application Category	Review category rules	A	60	Assuming a registered prescription medicine provided through LBS.
Other Activities	Develop relation with manufacturer (if applicable)	A	60	
	Label development and review	A	720	
Fees (initial)	Receive invoice	A	5	
	Check invoice	A	20	
	Process invoice	A	5	
Find literature, and seek permission for its use	Find and produce all required documents including: clinical, safety, and quality reference materials; risk management plan; summary documents; cover letters.	A	Out of Scope	Note second assumption above.
LBS search strategy	Document search strategy and seek agreement with TGA	A	960	
Poisons scheduling	Confirm that their product meets the current scheduling requirements under the Poisons Standard	A	60	
Compile eCTD dossier	Seek Electronic identifier	A	30	
	Compile Module 1	A	480	
	Compile Module 2-5	A	1920	
	Validate Dossier	A	120	
	Submit Dossier	A	120	
Round 1 evaluation	Review Clinical, Safety, & Quality reports	A	1920	
	Respond to questions	A	960	
Round 2 evaluation	Review Clinical, Safety, & Quality reports	A	1920	
	Respond to questions	A	960	
Delegate Overview & Product Information	Review delegates overview & prepare response	A	960	
Transparency	Negotiate with Delegate final version of PI	A	180	
ARTG Issued	Agree AusPAR	A	240	
	Log-in/download certificate	A	10	

	Review certificate	A	30	
	File/distribute certificate	A	30	
Fees (ongoing)	Receive invoice	A	5	
	Check invoice	A	20	
	Process invoice	A	5	
Post-market activities	Maintain relationship with manufacturer	0	30	
	Ensure information is available (maintaining accurate records), cognisant of any changes to legislation/guidance	0	30	
	Meet labelling/advertising requirements	0	30	
	Post-market surveillance	0	120	
	Report adverse events	0	30	
	Assist in investigations of adverse events	0	30	
	Take corrective action as applicable to fulfil compliance requirements	0	30	
	Provide information as required by the TGA for a post market compliance review (including provision of samples)	0	0	
	Maintain distribution records and other additional conditions of listing	0	0	
	Adhere to conditions of inclusion	0	30	
Total (minutes) for application			11800	
Total (hours) for application			197	
Cost to complete application			\$17,338	
Total (minutes) for ongoing			330	
Total (hours) for ongoing			6	
Cost ongoing			\$485	

### *Future population considerations (ARTG registration)*

The TGA has advised that, due to favourable market opportunities (outlined above), 5 (new or existing) Sponsors may submit applications for inclusion in the ARTG over the 10-year lifetime of the regulatory costing.

Sponsors will likely need to register more than one entry on the ARTG to include variations in strength (concentration) and flavours. TGA advice noted that, based on product ranges for existing nicotine replacement products on the ARTG, it would be reasonable to expect 2 strengths and 3 flavours per sponsor product range. This would result in a total of 6 separate ARTG entries per Sponsor. However, Sponsors will be able to duplicate the majority of the paperwork and amend each application to incorporate the slight product differentiations. That is, of the required tasks, only fees (initial and ongoing), ARTG issued (certificate), and post market activities (see Table 11) will need to be carried out in their entirety for each ARTG application (430 mins). For the remaining tasks, Sponsors can easily duplicate their first application and merely vary the appropriate sections (i.e. strength and flavour). As such, each Sponsor will be required to spend 11,800 minutes on their initial application, and a further 2,150 minutes on the remaining 5 applications (combined). Therefore, a total of 13,950 minutes will be spent, per Sponsor to complete and submit ARTG applications over the life of the regulatory costing.

It is important to note that there remains a possibility that the TGA will reject nicotine applications for inclusion on the ARTG due to a lack of efficacy, as research (evidence) on nicotine as a smoking cessation aid may not be sufficient. Thus, the above determination of population may be a slight overestimation.

## Regulatory costing

### Key assumptions

§ It will take a year for the first product to be registered on the ARTG (advice provided from the TGA regarding average time for a new product to be registered)

### Inputs

§ Number of sponsors including products on the ARTG = 5

§ Time required for each sponsor to enter all products on the ARTG = 13,950 minutes

### Future population (sponsors)

*Step 1.* Calculate total time in minutes to fulfil regulatory requirement:

§ ARTG listing: number of Sponsors likely to enter product on the ARTG (5) x time required to enter products on the ARTG (13,950 minutes) = 69,750 minutes

*Step 2.* Calculate total time in hours to fulfil regulatory requirement:

§  $69,750/60 = 1,163$  hours.

*Step 3.* Apply the hourly rate to determine overall regulatory compliance cost:

§ **Total cost for sponsors to register e-cigarette nicotine on the ARTG**  
=  $1,163 \times \text{hours} \times \$88.16 = \$102,486$

## Overseas purchase and Personal Importation Scheme

### Overview



Post the proposed regulatory changes, the legal possession of e-cigarette nicotine in Australia is dependent upon obtaining a valid prescription. There are no known legal impediments to e-cigarette nicotine users purchasing and using e-cigarette nicotine for

non-therapeutic use whilst travelling overseas. However, if they wish to enter Australia with e-cigarette nicotine in their accompanied baggage (under the ‘Personal Importation Scheme’ – which limits them to 3 month’s supply)<sup>214</sup> they need to be in possession of a valid prescription/doctor’s letter (note this does not need to be from an AP) or appropriate pharmacy labelling if the product had previously been purchased in Australia.

If a package containing e-cigarette nicotine is detected at the border by the ABF, then the standard process, in general terms, is as follows:

- § the ABF detects a good that could breach the TG Act
- § the ABF refers the good to the TGA
- § the TGA writes to the importer requesting that they provide evidence (within a two-week timeframe) that the importation is lawful (the importer needs to provide the necessary documentary evidence to demonstrate a legal right to the good (in this case, a valid prescription))
- § if the importer provides sufficient evidence<sup>215</sup> to the TGA that the importation is lawful the TGA advises the ABF to release the good (and advises the importer (usually by email) of this decision – if not<sup>216</sup>, the TGA provides a letter to the ABF requesting them to seize the good.

If the ABF is requested to seize the good by the TGA, then the ABF seizure process is followed<sup>217</sup> (see Figure 5).

Noetic is unable to determine the likely detection rate at the border for e-cigarette’s legally imported to Australia under the Personal Importation Scheme. All that is required for release of the goods by the ABF is either:

- § the provision of a valid prescription to the TGA, or
- § the provision of contact information and seizure details (from the Notice of Seizure) and a short statement pertaining to the holding of a valid prescription (and likely a copy of the prescription) on the ‘Claim for return of seized goods’ (Form B144) provided to the ABF.

Noetic assesses that either documentary pathway should take no more than five minutes to complete. Noetic does not consider any arising regulatory burden likely to be material to the overall regulatory costing.

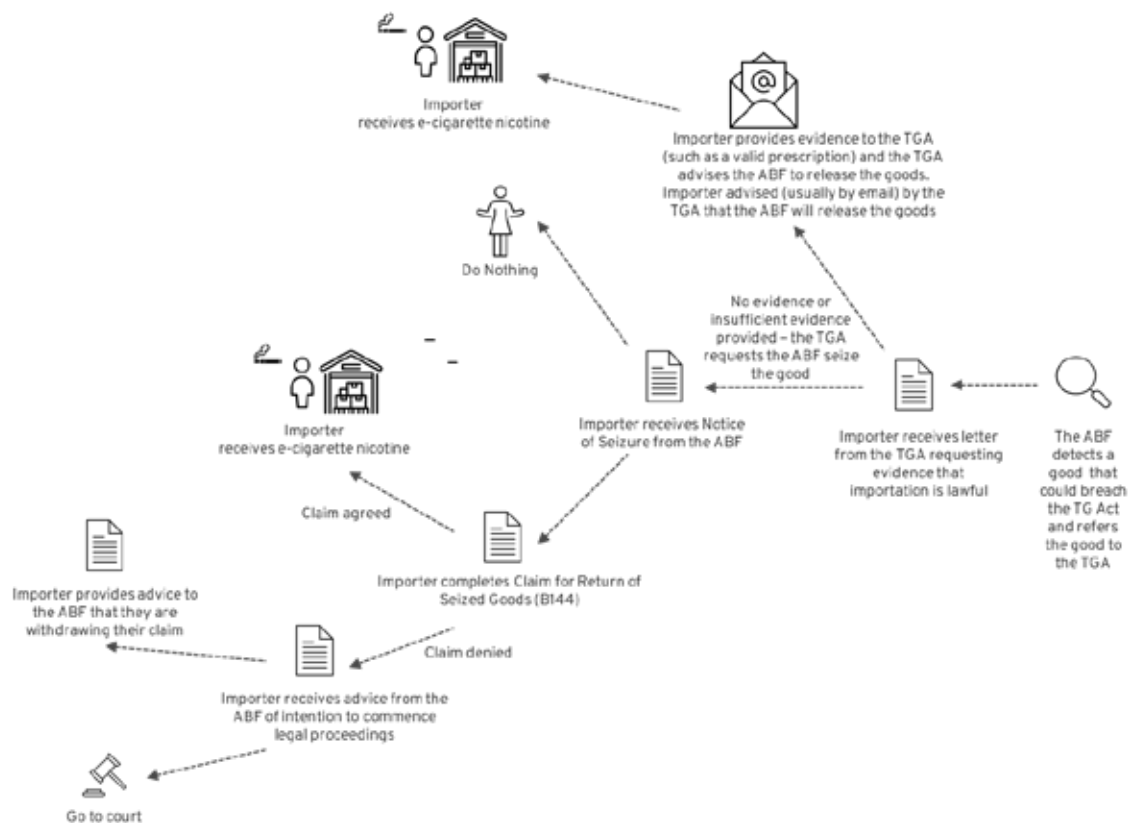
#### Figure 5. Border seizure flowchart

<sup>214</sup> Department of Health Office of Drug Control, ‘Travellers’, dated 18 December 2019, viewed 18 September 2020, <[www.odc.gov.au/travellers](http://www.odc.gov.au/travellers)>.

<sup>215</sup> The TGA has discretionary powers to provide a further opportunity for the importer to provide evidence in cases where there may have been an administrative error. Minor issues in the provision of evidence to the TGA will most likely be addressed via email with the importer.

<sup>216</sup> If on a subsequent occasion the same importer was requested by the TGA to provide evidence that the importation was lawful and they again failed to do so, then the TGA might consider an escalated compliance response to address recurrent contravening conduct. This might involve the issuing of an infringement notice or civil or criminal proceedings being brought against the importer.

<sup>217</sup> Additional information on the processes concerning the seizure of prohibited/restricted imports by the ABF are detailed on the ABF website (<[www.abf.gov.au](http://www.abf.gov.au)>).



Noetic considers it highly unlikely that any e-cigarette nicotine user will intentionally travel overseas for the sole purpose of purchasing e-cigarette nicotine (noting that even if they did, they could only bring back a maximum of 3-months' supply). This assessment is based on the prohibitive costs involved when e-cigarette nicotine users will be able to readily (and legally) purchase it domestically, as well as the current restriction on overseas travel (due to COVID-19). Additionally, even if e-cigarette nicotine users were to utilise this pathway to access e-cigarette nicotine, there would be no additional costs applicable to the regulatory costing (other than those associated with obtaining a prescription), as offshore activities are excluded.

If e-cigarette nicotine users arrived back in Australia with e-cigarette nicotine in their accompanied baggage, they would need to complete an Incoming passenger card and select the option that states that they are carrying 'Goods that may be prohibited or subject to restrictions, such as medicines, steroids, illegal pornography, firearms, weapons or illicit drugs?', as under the proposed regulatory change, e-cigarette nicotine will become a prohibited good (see the figure below).

Figure 6. Incoming passenger card

**Incoming passenger card • Australia**

PLEASE COMPLETE IN ENGLISH WITH A BLUE OR BLACK PEN

▶ Family/surname

▶ Given names

▶ Passport number

◆ Flight number or name of ship

▶ Intended address in Australia

State

▶ Do you intend to live in Australia for the next 12 months? Yes No

▶ If you are **NOT** an Australian citizen:

Do you have tuberculosis? Yes No

Do you have any criminal conviction/s? Yes No

**DECLARATION**  
The information I have given is true, correct and complete. I understand failure to answer any questions may have serious consequences.

PLEASE X AND ANSWER EVERY QUESTION – IF UNSURE, Yes X

▶ Are you bringing into Australia:

1. Goods that may be prohibited or subject to restrictions, such as medicines, steroids, illegal pornography, firearms, weapons or illicit drugs? Yes No
2. More than 2250ml of alcoholic beverages or 25 cigarettes or 25g of tobacco products? Yes No
3. Goods obtained overseas or purchased duty and/or tax free in Australia with a combined total price of more than AUD\$900, including gifts? Yes No
4. Goods/samples for business/commercial use? Yes No
5. AUD\$10,000 or more in Australian or foreign currency equivalent? Yes No

**Note:** If a customs or police officer asks, you must report travellers cheques, cheques, money orders or other bearer negotiable instruments of any amount.

6. Meat, poultry, fish, seafood, eggs, dairy, fruit, vegetables? Yes No
7. Grains, seeds, bulbs, straw, nuts, plants, parts of plants, traditional medicines or herbs, wooden articles? Yes No
8. Animals, parts of animals, animal products including equipment, pet food, eggs, biologicals, specimens, birds, fish, insects, shells, bee products? Yes No
9. Soil, items with soil attached or used in freshwater areas e.g. sports/recreational equipment, shoes? Yes No
10. Have you been in contact with farms, farm animals, wilderness areas or freshwater streams/lakes etc in the past 30 days? Yes No
11. Were you in Africa, South/Central America or the Caribbean in the last 6 days? Yes No

YOUR SIGNATURE

Day Month Year

**TURN OVER THE CARD**  
English








However, all returning passengers to Australia are already required to complete this card, and therefore this is an existing regulatory requirement and does not represent an additional activity as a result of the proposed regulatory change.

E-cigarette nicotine users will then be required to show the e-cigarette nicotine in its original packaging or a script from an Australian GP to the ABF. However, this should only take a very small amount of time, noting that this is unlikely to constitute additional time to clear the 'back of hall', as they may have other items that they need to declare and will likely be waiting to complete related activities. Therefore, no additional regulatory burden is generated by this activity.

## Option 4 (Combined)

### Overview

Table 12. Overview of Option 4 activities

REGULATORY ACTIVITY	Option 4 Options 2 and 3 Combined
Awareness	
Education	
Consultation with Doctor (to obtain script)	
Activities relating to obtaining e-cigarette nicotine (physical and online pharmacy visits)	
Authorised Prescriber Scheme + Special Access Scheme B	
Import Declaration	
Register e-cigarette nicotine on the Australian Register for Therapeutic Goods (ARTG)	

Option 4 includes Option 2 (education campaign) and Option 3 (scheduling) contemporaneously.

Thus, the total regulatory cost for Option 4 is the same as that detailed under Option 3 (=\$4.98 million), as Option 2 does not represent an additional regulatory burden.



## Conclusion

As per the Australian Government’s requirements and OBPR guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost. The following table provides the average estimated regulatory compliance costs arising from the proposed regulatory clarification.

**Table 13. Summary of estimated regulatory compliance costs**

Average annual regulatory costs (from business as usual) (\$million)				
Change in costs	Business \$	Community Organisation \$	Individual \$	Total change in costs
<b>Option 1</b>				
Status quo: Current therapeutic goods regulatory frameworks are appropriate - no clarification is required				
<b>Option 2</b>				
Public awareness campaign (stop initiation/dependence on e-cigarette/smoking cessation)				
<b>Option 3</b>	\$0.05		\$4.93	\$4.98
Clarification of the entry for nicotine in the Poisons Standard (including requirement for child resistant closure container)				
<b>Option 4</b>	\$0.05		\$4.93	\$4.98
<b>Options 2 and 3 combined</b>				

# ANNEX A: ACRONYMS AND ABBREVIATIONS

ABF	Australian Border Force
ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
ANZSIC	Australian New Zealand Standard Industrial Classification
AP	Authorised Prescriber
Customs Act	Customs Act 1901
ExCo	Executive Council
GP	General Practitioner
HREC	Human Research Ethics Committee
ICS	Integrated Cargo System
MBS	Medicare Benefits Scheme
OBPR	Office of Best Practice Regulation
ODC	Office of Drug Control
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
SAC	Self-assessed clearance
SAS B	Special Access Scheme B
Scheduling	TGA scheduling change
SUSMP	The Standard for the Uniform Scheduling of Medicines and Poisons
TG Act	Therapeutic Goods Act 1989
TGA	Therapeutic Goods Administration
WHO	World Health Organization
7CPA	Seventh Community Pharmacy Agreement

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