PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000031

Instructions given to the drafting office

Spoken

Senator: Jordon Steele-John

Question:
Are you able to share with the committee the instructions that you have given to the drafting office?

Answer:

The drafting instructions provided to the Office of Parliamentary Counsel are subject to legal professional privilege and cannot be shared with the Committee without compromising that privilege.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000032

2022 Vaping consultation

Spoken

Hansard page number: 50 – 2 May 2024

Senator: Jordon Steele-John

Question:

Would you be able to provide the committee on notice a list of those being consulted?

Answer:

The Therapeutic Goods Administration (TGA) has extensively engaged a broad range of stakeholders, including importers, manufacturers, wholesalers, pharmacies, healthcare professionals, consumer groups, the general public (including vapers), and public health organisations on the vaping reforms.

Bodies consulted

The TGA has a dynamic list of stakeholders on which it draws for formal consultation processes, webinars and ongoing engagement. This list includes over:

- 35 health professionals and health professional peak bodies, including the Royal Australian College of General Practitioners (RACGP), the Australian College of Rural and Remote Medicine (ACRRM), and the Australian Medical Association (AMA)
- 50 public health organisations, including the Cancer Council
- 25 academics, universities and research bodies

- 20 consumer groups and advocates, including the Consumer Health Forum and representatives from the primary and secondary education sector
- 40 importers, manufacturers, suppliers and industry peak bodies, and
- 30 vaping retailers and retail associations.

A number of these stakeholders made submissions and attended Committee hearings on the Inquiry into the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Vaping Reforms Bill).

Consultations on the vaping reforms

From 30 November 2022 to 16 January 2023, the TGA held a public consultation on the proposed reforms to the regulation of nicotine vaping products. Over 4,000 submissions were received from a range of stakeholders and stakeholder groups, including:

- state and territory health and education departments
- health professional bodies
- public health associations
- university researchers
- pharmaceutical industry and peak bodies
- vaping importers and manufacturers
- vaping retailers, including convenience stores and petrol stations
- pro-vaping associations
- individual healthcare professionals
- the general public, including individual vapers, current smokers and ex-smokers.

From 7 September 2023 to 21 September 2023, the TGA held a targeted consultation on the proposed reforms. Over 300 stakeholders were invited to participate in this consultation. These stakeholders comprised relevant stakeholders identified from previous consultations, who were invited to provide submissions. The TGA received 291 responses from a range of stakeholder groups including:

- retailers and retail associations
- importers, manufacturers, pharmaceutical wholesalers and distributors
- consumers, consumer groups and school related groups
- government agencies including state and territory health departments
- health professional peak bodies
- public health associations, and
- research and public health experts.

The two consultation processes included consideration of issues relating to the regulations and legislative instruments in the regulatory framework, including matters relating to the product standards.

A range of further consultation activities has occurred since the Minister announced the *Next steps on the vaping reforms* on 28 November 2023.

The TGA and the Office of Drug Control hosted a webinar on 12 January 2024 to discuss the impacts of the reforms to the medicinal cannabis industry. The TGA also hosted a further public webinar on 17 January 2024 to discuss the reforms. On 22 and 27 February 2024, the TGA held additional webinars with medical practitioners and pharmacists respectively.

A further targeted consultation was led by the TGA from 20 February 2024 to 10 March 2024, on the proposed requirements for therapeutic vaping devices and accessories. Over 90 stakeholders representing a range of interests, were invited to participate, including:

- healthcare professionals
- pharmacy supply chain (including wholesalers, pharmacies and pharmacists)
- manufacturers and suppliers of vapes
- universities and research institutes, and
- vape wholesalers and distributors.

More broadly, extensive consultation with states and territories has been undertaken throughout the development of the vaping reforms, principally through:

- the Health Ministers' Meeting
- its subordinate National E-cigarette Working Group, which comprises representatives from the Commonwealth, state and territory health agencies, and
- the newly established National Vaping Working Group, which comprises representatives from Commonwealth, states and territories health and law enforcement agencies). This National Vaping Working Group is co-chaired by the Commissioner of the Australian Border Force (ABF) Michael Outram and the Secretary of the NSW Ministry of Health Susan Pearce.

On 1 March 2024, the TGA consulted members of the National E-Cigarette Working Group on draft provisions of the Vaping Reforms Bill. Feedback from the exposure draft informed the final drafting of the Vaping Reforms Bill.

Following introduction of the Vaping Reforms Bill on 21 March 2024, consultations with key stakeholders on the vaping reforms have continued. These consultations have comprised:

- a webinar for key stakeholders
- one-on-one meetings with key stakeholders, and
- on-going engagement with the National E-Cigarette Working Group and the National Vaping Working Group.

The TGA intends to undertake further consultation with a broad range of stakeholders on the vaping reforms over the coming weeks and months.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000033

Submissions to the public vaping consultation

Spoken

Hansard page number: 55

Senator: Ross Cadell

Question:

As to the 4000 submissions you raised Dr Gilmour-Walsh, how many were campaign responses?
Do we know how many were campaign responses?
Can you take that on notice and try to get back to us?

Answer:

The Department understands that Senator Cadell's question relates to the number of campaign responses that were included in submissions made in response to the public consultation conducted by the Therapeutic Goods Administration on the proposed reforms to the regulation of nicotine vaping products between November 2022 and January 2023.

As advised by Dr Bridget Gilmour-Walsh at the Committee hearing on 2 May 2024, all submissions made in response to the public consultation were considered by the Therapeutic Goods Administration. No submissions were disregarded as part of the consultation process, despite some submissions appearing to have been made in very similar terms.

The Therapeutic Goods Administration did not tally the number of submissions that may have been campaign responses. However, a study examining the submissions was undertaken by researchers at the Melbourne Centre for Behaviour Change, University of Melbourne and the George Institute for Global Health, University of New South Wales.

The study found that 26% of submissions by self-reported e-cigarette users included text provided by an industry-led 'astroturfing' campaign.

This study is available at Perceptions of a prescription model for accessing nicotine vaping products: an examination of submissions made by self-reported e-cigarette users to an Australian consultation | Health Promotion International | Oxford Academic (oup.com) and is also at Attachment A.

All submissions received in response to the consultation, except those that contained inappropriate and abusive language, are available at Published responses for Proposed reforms to the regulation of nicotine vaping products - Therapeutic Goods Administration - Citizen Space (tga.gov.au).

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Article

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Article

Perceptions of a prescription model for accessing nicotine vaping products: an examination of submissions made by self-reported e-cigarette users to an Australian consultation

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Abstract

In response to rapid and substantial increases in rates of e-cigarette use among young people, Australia's Therapeutic Goods Administration (TGA) made changes to the regulations governing nicotine vaping products. As part of the regulatory change process, Australians were invited to comment on the proposed regulations, which featured the introduction of a prescription model for nicotine vaping products. To inform strategies to enhance compliance with the tightened regulations, this study examined submissions made by self-reported e-cigarette users to the TGA's public consultation (n = 1405). A content analysis was conducted to identify and quantify key arguments. Claims about possible negative consequences associated with the regulations (e.g. people will return to smoking, inconvenience) featured in most submissions (84%). Around half (55%) of submissions mentioned perceived benefits of e-cigarettes, including favourable health outcomes (e.g. improved breathing) and enhanced tobacco cessation. Around half (52%) featured concerns about inconsistency in treatment and the argument that e-cigarettes should not be restricted when more harmful tobacco products are readily available. Alternative approaches to a prescription model were offered in nearly one-third (31%) of submissions. One-quarter (26%) included text provided by an industry-led astroturfing campaign. The arguments made in the analysed submissions suggest a lack of appreciation of (i) the negative health outcomes associated with e-cigarette use and (ii) evidence linking these devices to smoking relapse. Results highlight the need for targeted health campaigns that address (i) gaps in consumers' knowledge and (ii) vaping-related misinformation being promulgated by the industry and its allies.

Keywords: e-cigarettes, nicotine, policy, consultation, Therapeutic Goods Administration

INTRODUCTION

Australia's approach to regulating e-cigarettes is among the strictest in the world, with nicotine-containing products legally available only via medical prescription (Greenhalgh *et al.*, 2022). E-cigarettes that do not contain nicotine are less restricted, and may be sold by retailers to those aged 18+ years in all states and territories except Western Australia (Greenhalgh *et al.*, 2022). The regulations relating to nicotine e-cigarettes are consistent with a precautionary approach to public health (World Health Organization, 2004). Such an approach involves taking action to prevent the harms associated with e-cigarettes given ongoing uncertainty about the benefits and long-term risks associated with use of these products. Consistent with tobacco industry exploitation of tobacco control laws (Moodie *et al.*, 2022; Watts *et al.*, 2021), there is

Contribution to Health Promotion

- We identified arguments made by self-reported e-cigarette users in submissions to a consultation on e-cigarettes.
- A prescription model was described as having numerous negative consequences, and many submissions focussed on perceived benefits of e-cigarettes.
- Content from an industry-led astroturfing campaign was detected in a substantial minority of submissions.
- To increase compliance with regulations, health communications could inform users of the risks associated with vaping.
- To prevent public policy from being influenced by vested interests, health organizations must expose disingenuous, industry-backed 'grassroots' campaigns.

evidence to suggest that Australia's regulations relating to e-cigarettes are being circumvented by commercial interests (Bara *et al.*, 2023; McCausland *et al.*, 2021; Scott *et al.*, 2023).

Australia's regulations in relation to e-cigarettes were developed following concerning increases in rates of use among young people. Use of the devices among adolescents increased from 4.3% in 2013 to 9.6% in 2019 (Australian Institute of Health and Welfare, 2020), prompting Australia's Therapeutic Goods Administration (TGA) to make changes to the regulations governing nicotine vaping products to reduce their accessibility. This involved the TGA making it illegal to purchase nicotine e-liquid or e-cigarettes that contain nicotine e-liquid without a prescription from a medical practitioner, regardless of whether the intended use is for therapeutic purposes. In addition to the health consequences associated with use among youth, the TGA cited several other reasons for proposing these changes (Therapeutic Goods Administration, 2020). These included the (i) lack of evidence supporting e-cigarettes as a safer alternative to currently available smoking cessation aids, (ii) insufficient evidence linking e-cigarette use with successful smoking cessation, (iii) potential for nicotine addiction in new or continuing users and (iv) need to implement effective measures for preventing and reducing nicotine addiction (Therapeutic Goods Administration, 2020), as per the World Health Organization's Framework Convention on Tobacco Control (World Health Organization., 2003).

As part of this regulatory change process, the TGA consulted Australians regarding its proposal (Therapeutic Goods Administration, 2020), allowing public health organizations, industry and industry front groups and the general public to comment on e-cigarettes and how they should be regulated. To provide a greater understanding of views on the Government's attempts to restrict widespread availability of nicotine vaping products, the present study aimed to identify and quantify the arguments made by self-reported e-cigarette users in their submissions to the TGA's consultation. Results have the potential to inform strategies to enhance compliance with the tightened regulations.

METHOD

This research was approved by a university Human Research Ethics Committee. Publicly available submissions to the TGA's consultation on the introduction of a prescription only model for nicotine vaping products were downloaded (n = 2385). Of these, 1405 were submitted by those who (i) self-identified as users of e-cigarettes and (ii) provided their views on the TGA's proposal. One researcher (M.J.) read all submissions in their entirety and used an inductive approach to identify coding categories, which were subsequently defined in a codebook. During this initial sweep of the data, the use of identical text across submissions was observed. Further exploration revealed this text to be from a template provided by an industry-led organization as part of an astroturfing campaign encouraging e-cigarette users to voice their opposition to the TGA's proposal. Verbatim text from this campaign was added to the codebook to facilitate identification, along with a link to the campaign's website.

Authors M.J. and A.R. independently coded 200 submissions according to the developed codebook, met to discuss instances of disagreement, and then independently coded the remaining submissions. Cohen's Kappa at the conclusion of all coding was 0.97, with a third coder (A.H.) resolving any discrepancies and consulting the two original coders as required.

RESULTS

The arguments made in the assessed submissions were categorized into topics. All topics are presented in Table 1, but only those identified in at least 10% of submissions are discussed below.

In most of the assessed submissions (84%), at least one potential negative consequence of the TGA's decision to introduce a prescription model for nicotine vaping products was nominated. Smoking relapse was most frequently reported (48%), followed by infringement on freedom of choice and personal liberties (24%) and the perceived inconvenience associated with accessing a medical practitioner for a prescription (22%). In a substantial minority of submissions,

Table 1: Arguments made in self-reported e-cigarette users' submissions to the TGA's consultation on introducing a prescription model for nicotine vaping products in Australia (n = 1405)

Code	*n*	%
Perceptions of the potential negative consequences associated with the TGA's decision	1178	84
People will go back to smoking	674	48
Decision infringes upon freedom of choice	332	24
Seeing a doctor for a prescription will be difficult/time consuming/inconvenient	303	22
Black market will emerge	276	20
Smokers will never quit/smokers who have quit will find it harder to stay quit	266	19
Seeing a doctor will burden the health system/cost taxpayers money	252	18
People will get sick and die	212	15
Will cost consumers more money	173	12
Youth will turn to cigarettes	131	9
Access to the variety of products needed to quit will be denied	66	5
Decision will increase appeal of use among youth because they want to rebel	42	3
Decision will burden the health system as people will go back to smoking	41	3
Destroy the vaping industry	24	2
Smoking rates will increase	21	2
Put pressure on justice system/enforcement	19	1
Claims made about the benefits of e-cigarettes/vaping	772	55
Vaping has beneficial health outcomes	601	43
E-cigarettes are an effective quitting aid	174	12
Vaping is cheaper/has financial benefits	129	9
How e-cigarettes make it easier to quit	95	7
95% factoid[a]	80	6
Vaping is proven to be safer than smoking	80	6
Users have greater control of content	35	3
Vaping reduces burden on the health system	33	2
Vaping is not harmful to others	29	2
Vaping is better for the environment	16	1
Inconsistent treatment	736	52
E-cigarettes should not be restricted when more harmful tobacco products are readily available/e-cigarettes should be as accessible as nicotine replacement therapies	671	48
A script is not needed for tobacco cigarettes or nicotine replacement therapies	259	18
Alternative policy and practice approaches	436	31
E-cigarettes should be available in retail stores	267	19
Tobacco cigarettes should be harder to access	94	7
E-cigarettes should be taxed instead	50	4
Vape store staff are experts/preferred providers of information	45	3
Youth should be educated on the harms associated with vaping	36	3
Industry-led campaign	370	26
Motivation behind legislation	236	17
Revenue raising by government	197	14
Government is in the pocket of Big Tobacco/Pharma	60	4
Ploy by Big Tobacco	11	<1
Bandwagon fallacy: need to legalize e-cigarettes as per other countries	231	16
Denial of evidence	174	12
Youth uptake is not a problem	103	7
Nicotine is not harmful	50	4

Table 1. Continued

Code	*n*	%
Gateway hypothesis/normalization is a fallacy	36	3
Only certain vapes are the problem	13	<1
Healthcare professionals are unwilling to prescribe or dispense e-cigarettes and are not trained in how to do so	172	12
Harm reduction at the individual level prioritized over the population level	105	8
Benefits of legalizing e-cigarettes	90	6
Better for kids to vape than smoke	38	3
Create jobs/benefit economy	33	2
Rates of cigarette smoking will decrease	27	2
Government ignoring evidence	52	4

Note. Proportions within and between codes do not add to 100% as submitters could make multiple arguments.
[a]Refers to the use of Public Health England's claim that e-cigarettes are 95% less harmful than smoking (McNeill *et al.*, 2015).

it was claimed the TGA's decision would result in the emergence of a black market (20%), make it harder for smokers to quit (19%) and/or burden the healthcare system (18%).

Around half (55%) of submissions featured claims about the benefits of e-cigarettes, specifically that (i) use has beneficial health outcomes (43%) and/or (ii) the devices are an effective quitting aid (12%). Around half (52%) mentioned inconsistent treatment, noting that e-cigarettes should not be restricted when more harmful tobacco products and other nicotine replacement therapies are readily available (48%).

One-third (31%) of submissions included suggestions for alternative approaches to policy and practice. For example, in 19% of submissions it was noted that e-cigarettes should not be restricted but rather made widely available in retail stores. Text from the industry campaign to legalize vaping was identified in one-quarter (26%) of submissions.

The motivation behind the TGA's decision was questioned in some submissions (17%), with the suggestion made that it was an attempt by the government to raise revenue and that the government was acting on behalf of tobacco industry lobbyists. In some submissions (16%) it was noted that Australia should adopt the approaches of countries such as New Zealand and the UK and legalize e-cigarettes. Just over 1 in 10 (i) countered scientific evidence that e-cigarettes are problematic (e.g. some submitters claimed that there is no youth uptake of e-cigarettes) and/or (ii) reported that healthcare professionals are unwilling to prescribe or dispense e-cigarettes and are not trained in how to do so.

DISCUSSION

The present study sought to examine submissions made by self-reported e-cigarette users to a public consultation on the introduction of a prescription model for vaping products in Australia. No support for the model was expressed in the analysed submissions, which is consistent with research indicating that those whose behaviours would be restricted are less likely to be supportive of proposed interventions than others (Diepeveen *et al.*, 2013).

The belief that a prescription model would have negative consequences, particularly smoking relapse, featured in most of the analyzed submissions. To counter this perception, it may be beneficial to inform the general public (and e-cigarette users in particular) that former smokers who use e-cigarettes have been found to be more than twice as likely to relapse than former smokers who do not use the devices (Baenziger *et al.*, 2021) and that dual use of e-cigarettes and tobacco cigarettes is not associated with reduced overall quit rates (Jackson *et al.*, 2020). It may also be useful to communicate research outcomes showing that a majority of those who use e-cigarettes to quit smoking continue to use the devices in the long term and that use of e-cigarettes for smoking cessation may lead to permanent nicotine dependence (Hanewinkel *et al.*, 2022).

Claims about the benefits of e-cigarettes, including favourable health outcomes (e.g. improved breathing) and that e-cigarettes are an effective quitting aid, were evident in many submissions. While there is evidence to suggest e-cigarettes are less harmful than tobacco cigarettes (National Academies of Sciences, Engineering, and Medicine, 2018), the long-term health risks associated with e-cigarette use remain unknown. Informing users about this uncertainty may assist them to make informed decisions about ongoing use. Given 40% of smokers who use e-cigarettes to quit smoking become users of both e-cigarettes and tobacco cigarettes (Kaplan *et al.*, 2021), ensuring users are aware that complete cessation of tobacco cigarette smoking is needed to optimize health benefits is also warranted (Stokes *et al.*, 2021). Cutting down on the number of

cigarettes smoked per day reduces the health risks of smoking by only a small amount (Chang *et al.*, 2021), and those who smoke even one cigarette per day are at substantially increased risk of experiencing a heart attack and stroke (Hackshaw *et al.*, 2018). Correcting misperceptions among dual users who may mistakenly believe they have markedly reduced their risk is warranted.

In many submissions, concerns were expressed about inconsistency between the regulatory treatment of e-cigarettes and tobacco products. In these submissions, attempts were made to discredit the TGA's proposal by arguing that nicotine replacement therapies and more harmful tobacco cigarettes are widely available. In a substantial minority of submissions it was argued that e-cigarettes should be available in retail stores. Communications highlighting (i) the historical mistake of tobacco cigarettes being made consumer products, (ii) the urgent need to reduce the accessibility and availability of both tobacco and e-cigarettes rather than increase the accessibility and availability of e-cigarettes and (iii) that nicotine replacement therapies have been approved by the TGA and are thus subject to quality and safety standards (unlike e-cigarette products) may be useful. Ongoing messaging communicating that e-cigarettes have not been approved by the TGA and have therefore not undergone rigorous testing for effectiveness, quality and safety may assist with ensuring users are adequately informed of the risks associated with use. Informing users of the differences in risks associated with use of e-cigarettes and approved nicotine replacement therapies (e.g. mouth sprays and inhalators) has the potential to go some way towards alleviating concerns over the apparent contradictions in the current availability of these products.

The degree to which content from an industry-led astroturfing campaign promoting the legalization of e-cigarettes appeared in analyzed submissions is concerning and evidences the continued attempts of the tobacco and e-cigarette industries to sway public policy in a manner that protects their financial interests. By lobbying users to make submissions on their behalf, the tobacco and e-cigarette industries are bypassing conflict of interest declaration requirements. Exposing the disingenuous methods used by industry to promote their agenda may assist with ensuring public policy is not influenced by vested interests. Given in some submissions it was noted that the TGA's proposal was evidence the Australian Government was in the pocket of Big Tobacco, communications that expose Big Tobacco as being behind much of the push to legalize vaping may address this misperception.

It is concerning that some submissions featured content denying scientific evidence showing that e-cigarettes are problematic. This finding evidences the proliferation of vaping misinformation, especially claims that youth e-cigarette use is intentionally exaggerated and use is not addictive (Sidani *et al.*, 2022). Strategies to address these claims, and misinformation generally, are urgently needed.

Finally, arguments that healthcare professionals are unwilling to prescribe or dispense e-cigarettes and are not trained in how to do so warrant further investigation. The effectiveness of the prescription model is dependent on general practitioners being open to prescribing e-cigarettes to smokers who wish to quit smoking but have been unable to do so with first-line treatments. The Royal Australian College of General Practitioners has developed resources to assist practitioners with providing evidence-based support to their patients. Ensuring practitioners are aware of these resources may assist in reducing any hesitancy to prescribe e-cigarettes for those who may benefit.

The present study had some limitations. First, the results cannot be considered to represent the beliefs of all e-cigarette users. Only a fraction of Australian vapers made a submission and it is probable that those who strongly opposed the TGA's reform were more likely to make a submission than those who were neutral or supportive. Second, although we were able to identify at least 26% of submissions that were influenced by an industry-led astroturfing campaign, it is likely that more may have been influenced by this and related campaigns, but did not use text that could be readily identified. Third, e-cigarette user status was self-reported and could not be independently verified. It is possible that some submissions were made by industry under the guise of being consumers. Finally, it was not possible to assess whether arguments differed by sociodemographic characteristics because submitters were not required to provide this information.

CONCLUSION

The present study identified and quantified the arguments made by e-cigarettes users who submitted responses to a proposal to implement a prescription model for nicotine vaping products in Australia. Health communications could inform users of the risks associated with vaping, including the potential for smoking relapse, and advise that e-cigarettes have not been approved by a medical authority and have therefore not undergone rigorous testing for effectiveness and safety. These communications could also be used to address misinformation, especially claims downplaying the issue of youth uptake. Such an approach could assist in reducing potential barriers to compliance with e-cigarette regulatory policies, such as those recently announced by the Australian

Government (Department of Health and Aged Care, 2023). Disseminating information in a manner that can be easily understood by the lay community is critical.

AUTHORS' CONTRIBUTIONS

M.J. made a substantial contribution to the conception and design of the work, and the acquisition, analysis and interpretation of data. She also drafted the work. A.R. and A.H. made substantial contributions to the analysis of the data. A.R., A.H. and S.P. made substantial contributions to the interpretation of the data and the writing of the manuscript. All authors agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

M.J. holds the position of Editorial Board Member for Health Promotion International. She was not involved in the review process for this manuscript nor the decision to accept this manuscript for publication.

ETHICAL APPROVAL

This research was approved by a university Human Research Ethics Committee (2022-22925-27027-3).

REFERENCES

Australian Institute of Health and Welfare. (2020) National Drug Strategy Household Survey 2019: Tobacco chapter—Online data tables. https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019/data (last accessed 7 February 2023).

Baenziger, O. N., Ford, L., Yazidjoglou, A., Joshy, G. and Banks, E. (2021) E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis. *BMJ Open*, **11**, e045603.

Bara, R. P. R., McCausland, K., Swanson, M., Scott, L. and Jancey, J. (2023) "They're sleek, stylish and sexy": selling e-cigarettes online. *Australian and New Zealand Journal of Public Health*, **47**. doi:10.1016/j.anzjph.2022.100013

Chang, J. T., Anic, G. M., Rostron, B. L., Tanwar, M. and Chang, C. M. (2021) Cigarette smoking reduction and health risks: a systematic review and meta-analysis. *Nicotine & Tobacco Research*, **23**, 635–642.

Department of Health and Aged Care. (2023) Taking action on smoking and vaping. https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping (last accessed 7 February 2023).

Diepeveen, S., Ling, T., Suhrcke, M., Roland, M. and Marteau, T. M. (2013) Public acceptability of government intervention to change health-related behaviours: a systematic review and narrative synthesis. *BMC Public Health*, **13**, 1–11.

Greenhalgh, E. M., Smith, L., Grace, C. and Scollo, M. (eds). (2022) 18.13 E-cigarettes and other alternative nicotine products: legal status in Australia. Cancer Council Victoria. https://www.tobaccoinaustralia.org.au/chapter-18-e-cigarettes/18-13-legal-status-in-australia (last accessed 7 February 2023).

Hackshaw, A., Morris, J. K., Boniface, S., Tang, J. L. and Milenković, D. (2018) Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports. *BMJ*, **360**, j5855.

Hanewinkel, R., Niederberger, K., Pedersen, A., Unger, J. B. and Galimov, A. (2022) E-cigarettes and nicotine abstinence: a meta-analysis of randomised controlled trials. *European Respiratory Review*, **31**, 210215.

Jackson, S. E., Shahab, L., West, R. and Brown, J. (2020) Associations between dual use of e-cigarettes and smoking cessation: a prospective study of smokers in England. *Addictive Behaviors*, **103**, 106230.

Kaplan, B., Galiatsatos, P., Breland, A., Eissenberg, T. and Cohen, J. E. (2021) Effectiveness of ENDS, NRT and medication for smoking cessation among cigarette-only users: a longitudinal analysis of PATH Study wave 3 (2015–2016) and 4 (2016–2017), adult data. *Tobacco Control*, **32**, 302–307.

McCausland, K., Maycock, B., Leaver, T., Wolf, K., Freeman, B. and Jancey, J. (2021) "Is it banned? Is it illegal?": navigating Western Australia's regulatory environment for e-cigarettes. *International Journal of Drug Policy*, **94**, 103177.

McNeill, A., Brose, L. S., Calder, R., Hitchman, S., Hajek, P. and McRobbie, H. (2015) E-cigarettes: an evidence update. Public Health England, London. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

Moodie, C., Hoek, J., Hammond, D., Gallopel-Morvan, K., Sendoya, D., Rosen, L. *et al.* (2022) Plain tobacco packaging: progress, challenges, learning and opportunities. *Tobacco Control*, **31**, 263–271.

National Academies of Sciences, Engineering, and Medicine. (2018) *Public Health Consequences of E-cigarettes*. The National Academies Press, Washington, DC.

Scott, L., McCausland, K., Maycock, B. and Jancey, J. (2023) The emergence of e-cigarette retail shops in a regulated tobacco control environment. *Health Promotion Journal of Australia*, **34**, 185–192.

Sidani, J. E., Hoffman, B. L., Colditz, J. B., Melcher, E., Taneja, S. B., Shensa, A. *et al.* (2022) E-cigarette-related nicotine

misinformation on social media. *Substance Use & Misuse*, **57**, 588–594.

Stokes, A. C., Xie, W., Wilson, A. E., Yang, H., Orimoloye, O. A., Harlow, A. F. *et al*. (2021) Association of cigarette and electronic cigarette use patterns with levels of inflammatory and oxidative stress biomarkers among US adults: Population Assessment of Tobacco and Health Study. *Circulation Journal*, **143**, 869–871.

Therapeutic Goods Administration. (2020) Notice of an interim decision to amend the current Poisons Standard. TGA, Canberra. https://www.tga.gov.au/resource/notice-interim-decision-amend-current-poisons-standard (last accessed 7 February 2023).

Watts, C., Burton, S. and Freeman, B. (2021) 'The last line of marketing': covert tobacco marketing tactics as revealed by former tobacco industry employees. *Global Public Health*, **16**, 1000–1013.

World Health Organization. (2003) WHO Framework Convention on Tobacco Control. https://fctc.who.int/ (last accessed 7 February 2023).

World Health Organization. (2004) The precautionary principle: protecting public health, the environment and the future of our children. WHO, Geneva. https://apps.who.int/iris/bitstream/handle/10665/346211/9789289010986-eng.pdf?sequence=1&isAllowed=y (last accessed 7 February 2023).

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Cancer Australia

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000034

Presence and other uses of chemicals found in e-cigarettes

Spoken

Hansard page number: 16-17

Senator: Matthew Canavan

Question:

Senator CANAVAN: I've just got a very written question that goes to this issue of carcinogens. In your submission, you say:

Whilst the evidence for risk association between e-cigarettes and cancer is limited and inconclusive, common chemicals in e-cigarettes are classified as a carcinogenic.

You've got a footnote there of 21 to 23. I've gone and looked at the references in the footnotes. There are three separate references. The references in 22 and 23 just seem to be the listing of certain chemicals, I presume. You mentioned earlier that the International Agency for Research on Cancer has listed these as carcinogenic. The reference in 21 is a paper titled 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers'. I've looked at that paper, and there is no mention of carcinogenic chemicals—there is no mention of any of those chemicals—in vapes. Maybe you could take it on notice, but can you point me to somewhere in that paper that indicates those chemicals being in vapes and being carcinogenic?

Ms Howlett: We'll take that question on notice, because we'll need to go back to our submission and to the reference to answer your question.

Answer

The relevant paragraph of the Cancer Australia submission to the Inquiry stated:

There is strong evidence that among young non-smokers, uptake of smoking is increased by an average of 3-fold in e-cigarette users versus non-users. Whilst the evidence for risk association between e-cigarettes and cancer is limited and inconclusive, common chemicals in e-cigarettes are classified as a carcinogenic.

The references applicable to common chemicals in e-cigarettes being classified as carcinogenic are references 22 and 23 only (the International Agency for Research on Cancer (IARC) monographs). Reference 21 refers to the nature of the evidence on the risk of smoking uptake in e-cigarette users but does not include information about chemicals in e-cigarettes being classified as carcinogenic.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Cancer Australia

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000035

Chemicals contained in vape flavouring

Spoken

Hansard page number: 17

Senator: Matthew Canavan

Question:

Senator CANAVAN: Okay. More generally then on this issue, are those chemicals you've identified—I think there are four of them; I wouldn't be able to pronounce them anyway if I tried—in all vapes or some vapes? Are they allowed in the prescription vapes?

Prof. Milch: They're not in all vapes. All vapes are different. That's part of the problem—the colourings, the flavourings, of vapes are unregulated, and there are different chemicals in many different vapes. As to whether those four chemicals are in the vapes that are to be prescribed, I think we'd need to take that on notice.

Answer:

The chemicals identified in these IARC monographs are not included in the Therapeutic Goods Administration (TGA) guidance on ingredients which must not be added in unapproved therapeutic vaping substances or therapeutic vaping substance accessories, or the list of prohibited ingredients in Schedule 1 of the legislation. Further questions about chemicals allowed in prescription vapes should be referred to the TGA.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Cancer Australia

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000036

Chemicals in vapes and other products

Spoken

Hansard page number: 17

Senator: Matthew Canavan

Question:

Senator CANAVAN: There is a list of prohibited ingredients in Schedule 1 of the legislation that allows for prescription vapes, and there are eight prohibited ingredients. None of them seem to be the four chemicals identified in your submission. Do you think they should be added to that list? Have you looked at that list? Do you know why they aren't on that list if they're carcinogenic and an issue?

Prof. Milch: I think we'd have to take that list on notice and get back to you.

Answer:

The list of prohibited ingredients in prescription vapes is a matter for the Therapeutic Goods Administration (TGA).

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Cancer Australia

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000037

Chemical in vapes and other products such as foods and medicines

Spoken

Hansard page number: 17

Senator: Matthew Canavan

Question:

Senator CANAVAN: Okay. Are these four chemicals—as I say, I can't really pronounce them—that you've mentioned used in other legal products like foods, medicines et cetera?

Prof. Milch: Once again, we'd have to take that on notice. We'd have to look that up.

Senator CANAVAN: This is a different issue, though. I just want to clarify. What I'm asking is whether those chemicals are used in other legal products—not illegal products but foods, pharmaceutical products et cetera.

Prof. Milch: We'll take that on notice.

Answer:

Further information about these chemicals can be found in the IARC monographs referenced in the Cancer Australia submission, including use in food production, agriculture, industry and medicines.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs Legislation Committee

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

01 May 2024

PDR Number: IQ24-000038

Referral pathway for children and young people who are vaping

Written

Senator: Louise Pratt

Question:

1. Would you support a referral pathway to doctors and school nurses for children and young people who are vaping, or have a suggestion for an alternative mechanism?

Answer:

1. Referral pathways to health professionals for people who are vaping, including children and young people who are vaping, are an implementation strategy in relation to the proposed legislation and are better referred to the Department of Health and Aged Care.

The Royal College of Australian General Practitioners (RACGP)'s *Guidance updates on smoking and vaping cessation support related to changes to Australia's vaping regulation* contains information for doctors on how to use e-cigarettes to assist patients with smoking cessation and on how to assist patients who are seeking help to quit vaping, including on how to provide this support to adolescents.[1]

[1] RACGP Supporting smoking cessation: A guide for health professionals accessed at www.racgp.org.au/getmedia/2f8ffac1-8751-41aa-906f-f0ec7feca048/RACGP-NVP-and-Vaping-Cessation-Consultation-provisional-draft-Dec2023.pdf.aspx