JUUL Labs: Submission to the Health Selection Committee

Smokefree Environments and Regulated Products (Vaping) Bill

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Thank You

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Introduction

JUUL Labs thanks the Associate Health Minister Jenny Salesa (the "Minister"), the Government and the Parliamentary Health Select Committee (the "Committee") for an opportunity to comment on the Smokefree Environments and Regulated Products (Vaping) Amendment Bill (the "Bill").

The New Zealand Context

New Zealand has set a target of reducing smoking to less than 5% of the population through Smokefree 2025 and has, so far, recorded impressive results in achieving 85% smokefree.

Around 14.2%² of New Zealanders smoke, a reduction by half from 25% in 1996/97³. Of those who continue to smoke, the Ministry of Health (the "MOH") notes that around "80% of current smokers would never have taken up smoking if they could have their life over"⁴. While the decline in smoking prevalence over the past two decades is significant, smoking combustible cigarettes continues to have a negative impact on public health.

Every year, around 5,000⁵ adults in New Zealand die prematurely as a result of smoking-related illnesses. Research published in 2016 by the MOH also shows that the negative economic impact of smoking was estimated at around 1.1% of GDP or \$NZD1.7b in 2004, rising to \$NZD2.5b in 2014.⁶ The New Zealand Treasury estimates the intangible cost of smoking to be between \$3.11b and \$11.2b⁷.

While the downward trend in smoking is encouraging, the proportion of adult Māori smokers remains disproportionately high, at around 34%, and 24% for Pasifika adults who smoke.⁸ This continues to remain a concern given that in 2012 about 39% of the Māori population smoked, meaning there has only been a decline of about 13% in seven years.

The MOH reported to Cabinet, in April 2016¹⁰ that:

"In 2012/13 New Zealand's Quitline supported 50,297 quit attempts. Quitline achieved a 24.2 percent self-reported quit rate at 3 months and 20.9 percent at 12 months. Māori rates and Pasifika rates were lower at 16.4 percent and 18.9 percent respectively at 12 months."

Ministry of Health (2019) Annual Update of Key Results 2017/18: New Zealand Health Survey. Wellington: Ministry of Health. Retrieved 15 May 2019 from https://minhealthnz.shinyapps.io/nz-health-survey-2017-18-annual-data-explorer/_w_0811ceee/_w_123fb24c/#!/home)

² Ministry of Health. (2019). <u>New Zealand Health Survey 2018/19 annual data explorer</u> Key Indicators. Current smoking. Wellington: Ministry of Health.

³ Ministry of Health. (2014). *Tobacco use 2012/13. NZ Health Survey*. Wellington: Ministry of Health.

⁴ Ministry of Health. (2020). <u>Stop Smoking</u> para. 2. Wellington: Ministry of Health

⁵ Ministry of Health. (2020). <u>Health Effects of Smoking</u> para 2. Wellington: Ministry of Health

⁶ O'Dea D, Thompson G et. al. 2207. *Report on Tobacco Taxation in New Zealand*. Smokefree Coalition. ASH. Ministry of Health. (2016). *Appendix Background Information: Tobacco Control Programme* p3, para. 4. Wellington: Ministry of Health

¹ Ministry of Health. (2016). Cabinet Paper. <u>Report Back on New Zealand's Tobacco Control Programme</u> p2, para. 17. Wellington: Ministry of Health

⁸ Ministry of Health. (2018). *Annual Update of Key Results 2017/18: New Zealand Health Survey*. Wellington: Ministry of Health

⁹ Ministry of Health (2014). <u>Tobacco Use 2012/13: New Zealand Health Survey</u> P11. Table 5: Current smoking among the total population aged 15 and above, by ethnic group and sex. Wellington: Ministry of Health

Ministry of Health. (2016). Cabinet Paper. <u>Report Back on New Zealand's Tobacco Control Programme</u> p5. Para.42. Wellington: Ministry of Health

JUUL Labs agrees with the MOH's statement that "it can be tough to quit smoking". 11

Nicotine is addictive and can be harmful, and smokers should first and foremost quit. But for those smokers who can't or won't quit, access to potentially less harmful alternative nicotine products than the combustible cigarette is critically important. Some adult smokers report that using Electronic Nicotine Delivery Systems ("ENDS"), of which vaping is a sub-category, can assist their transition from smoking. As highlighted by the explanatory note of the Bill, it "... acknowledges that vaping and smokeless tobacco products are less harmful than smoking and that they may help some people to quit smoking". Neither minors nor those without a history of tobacco use should use ENDS.

JUUL Labs's mission is to transition the world's one billion adult smokers away from combustible cigarettes. We pursue this mission while actively combating underage use of our products. JUUL Labs aims to actively support New Zealand's intention to further reduce the number of adult smokers. The industry needs a reset led by policymakers and regulators, and JUUL Labs is focused on building constructive relationships by listening and responding to the concerns of our stakeholders. We seek to earn the trust of society and build constructive relationships with regulators, policymakers and other stakeholders to gain a license to operate in New Zealand.

Our Submission

JUUL Labs supports the Government's Smokefree 2025 vision, specifically its focus on protecting underage people from exposure to tobacco marketing and promotion, reducing the supply and demand for tobacco products, and providing the best possible support for smokers to transition away from combustible cigarettes.¹³

JUUL Labs recognises, acknowledges and appreciates the opportunity to engage with the Committee in expressing its views. JUUL Labs is supportive of the Bill and comprehensive regulation of the category.

This submission is structured to reflect the key areas of concern the Government seeks to address with future regulations enabled by the Bill. This submission also reflects the Company's commitment to providing New Zealand's adult smokers with an alternative to combustible cigarettes to advance the Government's Smokefree 2025 vision.

JUUL Labs is committed to:

- Actively supporting the New Zealand government to achieve its Smokefree 2025 objectives;
- Combating underage use of JUUL products by restricting access and limiting appeal, including using technology to enhance age verification;
- Delivering high-quality products that provide a satisfying alternative for adult smokers who seek to transition away from smoking combustible cigarettes.

¹¹ Ministry of Health (2020). *Stop Smoking* para2. Wellington: Ministry of Health

¹² Smokefree Environments and Regulated Products Amendment Bill 2020 (222-1). (Explanatory Note) (General policy Statement) Para. 3. Wellington

Ministry of Health (2020). Smokefree Aotearoa 2025. <u>Achieving a smokefree 2025</u> Wellington: Ministry of Health

To deliver on our commitments, we have delayed the launch of JUUL products in New Zealand to ensure that we earn the trust of the government, the vaping category and New Zealanders by positively and transparently engaging in the consultation processes for this Bill.

This submission not only provides the Committee with our direct response to the Bill, but it also sets out our position on a range of regulatory issues. We have highlighted specific aspects of the Bill that we believe can be further enhanced or which may have unintended consequences.

As an organization deeply committed to helping smokers transition away from combustible cigarettes, our aim is to present opportunities through which the Government can maximise the benefits of the Bill and achieve its Smokefree 2025 objectives.

Executive Summary

Underage Use

- JUUL Labs supports the Government's intention to combat underage use.
- We support the Government's intention to set the minimum age for purchasing vaping products at parity with tobacco products.
- We support appropriate restrictions to limit access by underage people, both for offline and online purchases.
- We recognise that combating underage use requires an approach from multiple perspectives, including a responsible approach to advertising, promotion, flavours, and proper age verification prior to sale.
- We encourage the Committee to consider technology-based age verification in addition to the government's current proposals.
- We look forward to seeing regulations developed in this area and engaging with the MOH when it consults on them.

Promotion and Advertising

- JUUL Labs supports the Government's intention to limit appeal, particularly to underage people, by proposing restrictions on promotion and advertising.
- We note that an unintended consequence of restricting advertising and promotion may be that for those who have or are deciding to transition from combustible cigarettes, it may be more difficult to identify which vaping product suits their transition journey.
- We further note that very limited permissions for general retailers may potentially disadvantage adult smokers in rural areas who seek information and do not have access to specialised vaping retailers
- Packaging should inform and be visible to adult smokers at the point of sale so that they have the requisite information to consider transitioning away from combustible cigarettes.
- Packaging should include warning labels that nicotine is addictive.
- We are also concerned that restrictions in the Bill mean that only retailers, and not manufacturers, would be permitted to explain product features to adult smokers.

Product Safety

- JUUL Labs supports the Government's intention to impose product safety requirements.
- We support the annual testing for constituents of prescribed regulated products set out at cl.55
 of the Bill. Our view is that a good balance can be struck between public safety and commercial
 viability of continuous testing.
- We support regulation of product materials. Restrictions on ingredients should be proportionate to the reduced risk of vaping products and their ability to support smokers to transition away from combustible cigarettes.
- Public warnings proposed to be issued by the Director-General in relation to vaping products should be assessed by reference to the reduced harm they present relative to combustible tobacco products.
- We look forward to seeing regulations developed in this area and engaging with the MOH when it seeks the public's views.

Monitoring and Reporting

- JUUL Labs supports the Government's intention to impose monitoring and reporting requirements.
- We look forward to seeing detailed regulations developed in this area and to engaging with the MOH during the public consultation.

Product Notification

- JUUL Labs supports the premarket notification system proposed by the MOH to promote consumer protection.
- We observe that clearly defined regulations on how and when to notify (e.g. prohibited ingredients and flavours, significant changes) will more likely result in minimal burden to the industry while also allowing the MOH to manage the risks posed by the regulated products covered in the Bill.
- We look forward to seeing regulations developed in this area and engaging with the MOH during the public consultation.

Advice to Customers

- JUUL Labs supports provisions that would allow adult smokers to access advice to support their transition from smoking.
- We acknowledge the Government's desire to provide a balanced approach whereby adult smokers can access advice to support their transition from cigarettes while not normalising vaping in New Zealand.
- We look forward to seeing regulations giving structure and guidance on the Government's expectations with respect to advice and advertising/promotion.
- We are concerned that smokers in rural areas will not have access to advice and information due to the absence of specialised vaping retailers or where there is little awareness of, or access to, sources of information to support their transition from combustible cigarettes.

Flavours

- JUUL Labs welcomes the Government's choice to regulate, rather than ban, flavours.
- Scientific evidence shows that the availability of flavours can increase the success of transition from combustible cigarettes among adult smokers.
- We support the Government's intention to limit appeal of the category to underage people.
- We are concerned that only specialised vaping retailers will be permitted to sell a wide range of flavours. Adult smokers who have not already made a decision to transition are unlikely to visit a specialised vaping store, and are therefore not presented with a wider range of alternatives to combustible cigarettes.
- We would also then support amendments to the Bill that allow the sale of a wider range of flavours at general retail outlets.

Nicotine Concentration

- We recognise that the Government seeks to address nicotine concentration in forthcoming regulations.
- Our observations are that to increase the likelihood of adult smokers transitioning away from
 cigarettes, vaping products should be permitted to deliver nicotine at levels comparable to
 combustible cigarettes. In the case of JUULpods, our 59 mg/ml products deliver such levels,
 based on scientific data. Higher nicotine content products may be used by the most dependent
 smokers, who have the highest risk of smoking related damage, and who benefit most from
 transitioning to potentially less harmful alternatives.
- We would welcome the opportunity to provide further scientific studies and information on the impact of nicotine levels on the ability for adult smokers to transition away from combustible cigarettes.

Commentary by Policy Area

1. Underage Use

Combating Underage Use

JUUL Labs fully supports proposed amendments to restrict access to, and appeal of, vaping products to protect minors. Our customer base is the world's one billion adult smokers, and we do not intend to attract underage users. To earn a license to operate in society, we need to put stakeholder trust at the center of what we do and build constructive relationships with regulators, policymakers and other stakeholders. That begins by inviting an open dialogue, listening to others and being responsive to their concerns.

Minimum Age of Purchase

For the reasons above, it is not appropriate for underage people to consume nicotine and we support restrictions on the purchasing age of vaping products. We support the Government's intention to set the minimum age for purchasing vaping products at parity with tobacco products, which is currently 18 years of age.

Restricting Access

JUUL Labs recognise that preventing underage use requires action on multiple fronts, including but not limited to a responsible approach to advertising, promotion, flavours, and proper age-verification prior to sale. The Bill addresses many of the factors that contribute to the access and appeal of vaping products to minors.

We have implemented a variety of actions designed to prevent underage access to our products in every market in which we operate, including:

Retail Stores -

We contractually require authorised retailers to verify that customers are above the legal age prior to purchasing. In addition, we conduct retail training on age verification, and monitor compliance through independent mystery shopper agencies. Retailers found to be non-compliant face contractual penalties, including losing the authorisation to sell JUUL products.

Online sales restrictions -

Our owned e-commerce sites restrict underage purchases by using robust, independent ageand-identity-verification services to validate government-issued identification submitted by site visitors.

Our e-commerce sites also limit the quantity of products that a customer can purchase within a given period of time to mitigate the risk of an adult of legal age purchasing high quantities of product for distribution to minors.

Counterfeit and illicit trade -

We work with internet service providers and domain hosts to identify, report and take down websites that sell counterfeit and/or illicit JUUL and other vaping products in order to prevent illegitimate retailers from selling to underage people. We also collaborate with Instagram, Facebook, and other social media platforms, along with online marketplaces, to take down unauthorized third-party listings of JUUL products in an effort to block social selling of our products.

Tools for Preventing Underage Use

JUUL Labs is focused on developing technologically-based solutions to further restrict underage access and use of our products . Some tools we've pioneered in other markets include the following:

Devices that require age verification to activate -

At JUUL's owned retail store in Toronto, Canada, we conducted a limited test of a Bluetooth-enabled device that comes deactivated ("locked") at the point of sale. The locked device does not produce vapor until the device is activated and unlocked by the age-verified user and a JUUL retail staffer in-store using a proprietary tablet. This additional layer of verification that the consumer is of legal age reduces the risk of underage use, even in the event that a retailer does not age-verify at the point-of-sale.

Track and Trace -

Track-and-Trace is a system that works to identify where underage users obtain products. Track + Trace establishes this capability through (1) product serialization, (2) supply chain and distribution traceability, and (3) operation of a web portal for the public to report devices confiscated from underage audiences.

The goal is to trace a confiscated device back to the point of sale so the Company can partner with retailers to prevent potential sales to underage. If traceable products are confiscated by an adult, the Track + Trace system can identify where the product was sold, flag bad actors in the supply chain and take appropriate action to keep JUUL products out of the hands of underage minors.

Retail Access Control Standards (RACS) -

JUUL Labs has piloted with retailers in the U.S. a set of standards that are pre-programmed into existing point-of-sale (POS) technology solutions to facilitate automated (1) enhanced age-verification and (2) quantity purchase limit enforcement for every JUUL product transaction.

Whenever a transaction contains JUUL products, a RACS-compliant POS system will automatically (1) require scanning of a government-issued I.D. to verify age and that the I.D. has not expired; (2) limit quantities that can be purchased in a single transaction; and (3) integrate the sales transaction to prevent manual override by the retail sales associate ("clerk").

2. Promotion and Advertising

JUUL Labs supports the Government's approach to ensuring underage people are not exposed to promotion and marketing of vaping products.

We have halted all broadcast, print and digital product advertising and instead JUUL Labs only markets through point-of-sale displays, indicating the availability of JUUL products and pricing, as well as directly to first-party current adult users of tobacco products who are above the age of 21. In addition, JUUL Labs has discontinued the use of social media promotions since October 2018 and we have instituted additional controls to impede third-party social media promotions of JUUL products.

Despite the intentions of the advertising and promotions provisions of the Bill, we are concerned about some potential unintended consequences. Current smokers should be presented with information that challenges their smoking habit when purchasing tobacco products. Restrictions proposed in *Part 2* of the Bill provide a number of exemptions to prohibitions on the premise that they may not be promotional in nature, we address these below.

Advertising: Allow the general smoking public to access product information in the appropriate places

The Bill generally prohibits (in addition to the existing prohibitions on tobacco products) advertising and promotion for all vaping and smokeless tobacco product parts including vaping liquids except for campaigns pre-approved by the Director General of Health.

If legislation is to succeed in transitioning smokers away from combustible cigarettes and preventing smokers from reverting to combustible cigarettes, the general smoking public needs information so they can understand two key points:

- 1. Vaping products are potentially less harmful than combustible tobacco products; and,
- 2. Consumers should have access to factual product information to decide which vaping product can best support their own transition away from combustibles.

The Bill clearly sets out that vaping products are less harmful than combustible tobacco products. To ensure that adult smokers are well supported to transition from combustible tobacco products, we respectfully submit that manufacturers should be able to provide information about the features of their products to help adult smokers identify which products can best support their transition. We believe that it is important to take a different approach with vaping products than with combustibles for two reasons:

Vaping products are not all the same -

New Zealand smokers may find it genuinely daunting to identify which vaping products are right for them. Regardless of their preferences and habits, those who cannot make a dedicated trip to have a discussion with specialist retailers may inadvertently believe that all vaping products are the same regardless of intended functionality or purpose.

This may impact adoption and transition rates as, potentially, smokers may be unsatisfied with their initial vaping purchase and will continue to struggle with finding what suits them.

Some vaping products employ technological features which might reduce exposure to certain hazards. For instance, JUUL devices include robust temperature control elements designed to prevent the e-liquid from overheating, which could produce harmful or potentially harmful constituents in the aerosol. JUUL devices are also manufactured in facilities that exclude contaminants that could lead to shorts or device malfunction. And JUUL devices operate at relatively low wattage levels, as overheating can prevent malfunction or overheating. All JUUL e-liquid formulations also undergo rigorous clinical and pre-clinical testing to identify potential risks to the user.

JUUL Labs applies stringent controls to ensure product quality and safety and mitigate any potential risks to consumers, not all vaping devices or e-liquids however are developed with similar standards. We believe it is appropriate that manufacturers be permitted to communicate this relevant information so that consumers are better able to make informed choices when selecting vaping products.

Vaping products are constantly evolving -

The vaping category is evolving, as technology is rapidly developed to cater for the needs of an ever growing variety of smokers with different preferences and habits. As with all new technology, allowing reasonable and appropriate room for innovation, and allowing manufacturers to tell customers about this, is critical for future development and realising the Government's objectives to transition more smokers away from combustibles.

We therefore respectfully submit that the MOH be empowered to impose reasonable controls on advertising channels and content. However, by allowing manufacturers and retailers to discuss the features and advantages/disadvantages of non-combustible nicotine products in a regulated and appropriate forum, information regarding lower-risk products can reach smokers who would not be in a position to make a dedicated trip to specialist vape retailers. Controls on themes, placement, timing and media are appropriate to prevent and stop uptake by never and former smokers in general and underage minors.¹⁴

JUUL Labs agrees that public health agencies should continue to provide well-crafted communications to help current smokers make informed choices. The Committee may wish to consider providing further exemptions that allow retailers to use approved public health organisation communications in their retail premises.

Advertising and promotion in the context of product packaging

JUUL Labs accepts and supports the Government's intention to reduce the appeal of vaping products to never and former smokers and to prevent normalisation of vaping as anything other than as a means by which adult smokers can commence and sustain their effort to transition from cigarettes.

Product packaging can be both informative and promotional. Product packaging can play an important role for smokers in helping to inform their purchasing decision and providing information that supports

Disclaimer: This information is for policymakers and is not for advertising or promotional purposes or intended for a consumer audience.

¹⁴ See Bates C, Beaglehole R, Laking G, Sweanor D, Youdan B, <u>A Surge Strategy for Smokefree Actearoa 2025: The role and regulation of vaping and other low-risk smokefree nicotine products</u>, Auckland: ASH New Zealand and End Smoking New Zealand (2019), p. 26-27.

¹⁵ Ibid., p. viii.

making their decision to transition a successful and sustainable one. Being able to see vaping product packaging would help smokers to understand the alternatives available to them at retail premises.

Packaging labels, including warnings, need to convey accurate information that communicates relative risk. When applied to noncombustible tobacco and vaping products, warning labels traditionally prescribed to combustible cigarettes can lead to misinformation and deter smokers away from comparatively lower-risk alternatives. 16 Instead, warnings can be developed that explain relative risk when compared with smoking combustible cigarettes.

Advertising and Promotion in the context of manufacturers

The Bill appears to contemplate that it is only for retailers to advertise and otherwise give product information to adult smokers. Also, specialist vape retailers must, according to cl. 14A(2), sell vaping products at a permanent fixed structure.

Noting our comments above on permitting adult smokers to learn more about which products are right for them, we believe that manufacturers can also play a meaningful role in helping adult smokers understand the products they manufacture. Manufacturers often run informative websites intended to share product features and information with customers, and e-commerce sites for the purchase of such products. Manufacturers do not necessarily operate fixed owned retail locations and, therefore, would under the current Bill, be inadvertently precluded from discussing their products with adult smokers.

In order to address these concerns, we respectfully submit that the Committee considers recommending removing requirements for a fixed retail location in proposed criteria for specialist vape retailers under cl. 14A of the Bill.

3. **Product Safety**

Chemical, thermal, mechanical and electrical safety standards for devices and e-liquids are emerging internationally, and New Zealand is well placed to adopt them.

Manufacturing Facilities and Processes for Pods and E-liquids -All manufacturing activities, for the device or e-liquids, should occur in ISO 13485 certified facilities. All e-liquids and pods should be manufactured in ISO Class 8 clean rooms.

Manufacturing Facilities and Processes for Devices -

Products should be developed to resist alteration, tampering, or unintended use. Devices should be designed and manufactured using quality standards such as ISO Class 9 standards to minimise any potential risks or unintended consequences to users by controlling the introduction of contaminants. Device temperature control is an important safeguard to minimise the generation of harmful by-products in the aerosol produced because a higher temperature generates a higher level of harmful by-products. Device batteries should be manufactured to internationally recognised safety standards to prevent overheating or ignition.

¹⁶ Ibid, p. 34-36.

Ingredients -

Internationally recognised testing standards should be developed to screen e-liquids and aerosols for ingredients of potential concern. All ingredients in vaping products should be manufactured to appropriate purity standards. Ingredients should be produced in manufacturing facilities that can adequately exclude or control potential contaminants, aligned to international standards, such as ISO 9001.

Manufacturers of vaping products should be required to disclose ingredient listings and conduct testing on aerosol emissions. Regulators should make that information available to the public, as appropriate and in the context of relative risks.

Any restrictions on ingredients should be based on sound science, realistic exposure levels, and consideration of their potential to promote adult transition from combustible cigarettes and the relative risks of cigarettes.

Packaging -

Product design parameters must limit leakage or accidental spilling of nicotine-containing eliquid during product handling, as well as adoption of international child and tamper resistant packaging standards to mitigate potential for accidental nicotine exposure. Some of the measures include the adoption of a controlled flow rate of the refill vial nozzle; the use of a removable plastic seal; the existence of a silicon ring at sealing positions; the reduction in the steps needed to perform the refill and the use of warnings/leaflets to increase consumer caution during refilling.¹⁷

4. Monitoring and Reporting

Reporting Adverse Reactions

• We support the requirement for reporting of adverse reactions for notifiable products, as proposed in the Bill at cl.64 as this appears to be in line with international practices in markets such as Canada, the US and the European Union.

Provision of Sales Data

- We, in principle, support sharing of data with the MOH for public safety purposes. We also support proposals in the Bill at cl.73(3) that commercially sensitive data should be kept confidential. We propose to engage with the MOH to understand the intended purpose for collecting specific data and how it will be stored.
- We, in principle, support proposals at cl.76(7) and cl.94 (sharing of sales data, quantity sold, RRP, etc. per SKU for each calendar year may be asked for by regulation), on the assumption that the intended purpose of collection is for public policy purposes, the information remains in confidence with the MOH, and any published analysis will be at a category level.

¹⁷ C Vardavas and P. Behrakis, Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms, Directorate-General for Health and Food Safety, European Commission (Brussels, 2016), 9.

• We look forward to seeing regulations developed in this area and engaging with the MOH when it seeks the public's views.

We have no additional comments to make with respect to proposals in the Bill for the establishment of monitoring and reporting requirements.

5. Product Notification

A notification regime requires notification of specific products prior to marketing, with self-certification that the regulatory requirements have been met. A notification-based approach supports harm reduction because it holds manufacturers accountable to set-standards while facilitating efficient access to noncombustible nicotine products.¹⁸

Surveillance, adverse-reaction-reporting, and product oversight can be used to address product compliance and enforcement on an ongoing basis. We are pleased to see this in the Bill. As an example, the European Union (EU) has implemented a similar approach for vapor products.¹⁹

6. Advice to Customers

We support the intention to allow the provision of advice to adult smokers to support their effort to transition from cigarettes.

As indicated earlier in this submission, we are concerned that in achieving a balance between maximising the potential benefits of the category for adult smokers and preventing underage use, the Government's approach in this Bill might give rise to unintended disparities in the context of access to information on alternatives to combustible cigarettes.

Advice to Customers: Transitioning from combustibles is assisted where advice is easily accessible

To illustrate, and because we share the Government's objectives of transitioning adult smokers to less harmful alternatives, we would like to take the opportunity to share some insights we may have on the purchasing behaviour of adult smokers.

Data from the MOH's 2018/19 Annual Health Survey shows that only 3.2% of adults were regular electronic cigarette or vaping product users.²⁰ It appears to us that adult smokers who have already, or are in the process of deciding to, transition from combustibles may be more inclined to visit a specialist vaping store. Conversely, we believe that smokers who have not yet considered a transition from combustibles are correspondingly less likely to visit such stores and may, instead, continue to visit retail stores such as convenience stores and gas stations where they habitually purchase them.

We believe this may be because:

¹⁸ See Bates C, Beaglehole R, Laking G, Sweanor D, Youdan B, "A Surge Strategy for Smokefree Aotearoa 2025", p. 32-33.

¹⁹ Tobacco Products Directive (EC/2014/40).

²⁰ Ministry of Health. (2019). *Annual Update of Key Results 2018/19: New Zealand Health Survey*. Wellington: Ministry of Health.

- 1. Product advice is not generally available in the most convenient channels for purchase. The primary reason for vapers' channel of choice is convenience. Online and convenience stores (e.g. dairies and gas stations) are seen to be most convenient.²¹ For convenience stores, this appears to fit with the adult smokers behaviours as around 70% of scanned cigarette purchases come from these convenience stores. As for online purchases, based on data from the UK, the trend over time is that consumers are likely to move to online channels as they begin to understand what vaping products they prefer and which ones fit with their transition journey.²²
- 2. Regular users of vaping products are more likely to be located in metropolitan areas. ²³ Our observation is that this probably because that is where the vast majority of specialist vape stores, who can advise prospective users, are located. We estimate there are around 150 vaping stores throughout New Zealand. This compares with over 3,000 dairies and 750 gas stations. The proportion of dairies and gas stations ties closely with population numbers in regions. We are concerned that adult smokers in rural areas will not have access to advice where specialised vaping retailers are not present or where there is little awareness about sources of information to support their transition away from cigarettes.

We support the Government's intention to provide information and support to smokers who want to transition away from cigarettes. We respectfully suggest that having the opportunity to present information and advice about less harmful alternatives to adult smokers in a broader variety of channels may further encourage that transition.

Advice to Customers: Industry to be guided on what constitutes "advice"

As regulations are developed we look forward to seeing the Government's directions on what constitutes "advice" to consumers. We believe that clarity on permissible advice is needed.

For example, advice must not contain medicinal claims unless the product is duly authorised for those purposes and the claims scientifically substantiated and legally permissible. Vaping products may be presented as an alternative to combustible cigarettes but retailers must do nothing to undermine the message that quitting tobacco use is the best option for health. Medicinal claims would include smoking cessation and reduction claims, such as those seen in ads for licensed nicotine replacement therapies (NRT) and a product would need authorization before such claims could be made for it.

We hope that care is taken so as to not put retailers and manufacturers in a position where they are apprehensive or confused about an acceptable way of speaking to adult smokers looking to transition from combustible cigarettes. In that connection we also respectfully ask that the Committee also considers our broad observations on advertising and promotion above.

²¹ IRi. (2018). *Vaping in New Zealand: Cross-Channel Shopper Behaviour Study*. Auckland: IR.

²² Ibid.

²³ Ibid.

7. Flavours

The Regulatory Impact Assessment "Supporting smokers to switch to significantly less harmful alternatives" sets out two options²⁴:

Option One: status quo -

no specific power to prohibit flavours and/or colours, but the product safety provisions could be relied on to some extent

Option Two: legislative prohibition -

include in the SFEA a power to prohibit flavours and colours in vaping and smokeless tobacco products which attract young people to use the products.

We firmly support the Government's objective to prevent appeal of the category to underage people. We also support prohibiting the use of colourants in e-liquids that produce coloured vapour. On the issue of colourants, we note that these are also prohibited in the United Kingdom under Regulation 16(1)(c) of the Tobacco and Related Products Regulations 2016, a consequential implementation of the EU's Tobacco Products Directive 2004. We believe that the absence of coloured vapour will not be a major disincentive for smokers to transition from combustible tobacco products to vapour products.

Flavour Choice: Potential consequences when flavours are not accessible

While we are supportive of the Government's approach to flavours generally, we wish to respectfully highlight potential unintended consequences where availability is restricted to just specialist vape retailers. This is primarily because, in our view, it cannot be overlooked that flavours play a role in helping adult smokers transition away from smoking combustibles.²⁵ Research also shows that adults who use multiple e-liquid flavors and flavors other than tobacco and menthol are less likely to revert back to cigarette smoking. They are also less likely to be "dual users" (i.e. to continue the use of combustible cigarettes, rather than transitioning completely to vaping products).²⁶ As such, the responsible marketing of flavoured products can play a role in tobacco harm reduction.

Having a range of flavours readily available in places where adult smokers may make their decision to transition, i.e. general retail establishments, might lead to greater numbers of smokers choosing potentially less harmful products. We observe that the top three reasons why electronic cigarette users choose their channel of choice are: (1) convenience of location, (2) large offering of flavours, and (3) prices are low compared to combustible cigarettes.²⁷ We submit that it is important to not overlook the significance of that second category.

²⁴ Ministry of Health (2016), "Cover Sheet: Supporting smokers to switch to significantly less harmful alternatives" S3: "Options identification", p.23 "Issue 7: Use of flavours and colours that may attract young people to vaping and smokeless tobacco products". Wellington: Ministry of Health

²⁵ See for instance, Christopher Russell, Farhana Haseen, and Neil McKeganey, "<u>Factors associated with past 30-day abstinence from cigarette smoking in adult established smokers who used a JUUL vaporizer for 6 months</u>," *Harm Reduction Journal* 16, no. 59 (2019).

Dina Jones et al., "Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016–2017," Tobacco Regulatory Science 5, no. 6 (2019).

 $^{^{}m 27}$ IRi. (2018). Vaping in New Zealand: Cross-Channel Shopper Behaviour Study. Auckland: IR..

Permitting a wider range of flavours, through all retail channels, may also keep illicit trade of restricted products at bay. Bad actors may view restrictions as an opportunity to make illegal flavour, counterfeit, compatible, or diverted products that may pose health and safety risks available through channels that do not include age-verification requirements. In the UK, for example, surveys showed that vapers thought that banning flavoured liquids would deter them from using vaping products to help them quit or reduce their smoking; moreover, such prohibitions could also push current vapers towards illicit products.²⁸

For these reasons, we respectfully submit that the Committee considers a greater flavour diversity for general retail stores. We would support amendments to the Bill that allow the sale of a wider range of flavours at general retail outlets.

8. Nicotine Concentration

In order to maximize the harm reduction potential of vaping products, we respectfully suggest that they should be permitted to deliver comparable levels to mimic the experience of smoking and to promote moving away from cigarettes entirely.

The Royal College of Physicians in the UK highlights that "the ideal harm-reduction device should deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximizing palatability and nicotine delivery to approximate the experience of cigarette smoking more closely."²⁹

Our clinical studies have demonstrated that JUUL's 59 mg/mL pods deliver nicotine at peak levels, on average, similar to or lower than cigarettes, over a comparable number of puffs.³⁰

Our clinical studies of adult smokers have also found that after using a JUULpod (59 mg/ml), participants reported a reduction in the urge to smoke cigarettes that, while less than the reduction after smoking their usual brand cigarette, was still statistically significant.³¹ In an independent study comparing other Vaping Products with lower nicotine concentrations than a JUULpod (59 mg/ml) or at the EU Tobacco Products Directorate limit of 20mg/ml, the use of a JUULpod (59 mg/ml) relieved the urge to smoke and was rated significantly higher in several other subjective effects.³²

Providing a similar nicotine effect and experience to cigarettes is critical to facilitate a smoker's transition and ultimate switch from combustible use. Peer-reviewed research shows that JUUL's 59 mg/ml products help transition smokers away from cigarettes at high rates. A recent study evaluated US adults (21+ years) who were established current smokers of conventional cigarettes and recruited at their first purchase of a JUUL Starter Kit (59 mg/ml product) in a retail store or through JUUL's website.

Ann McNeill et al., *Vaping in England: an evidence update including mental health and pregnancy, March 2020*, Public Health England (London, 2020), p. 13.

²⁹ "Nic<u>otine without Smoke: Tobacco Harm Reduction,</u>" Royal College of Physicians, 2016.

Nicholas Goldenson et al., "(Poster) Pharmacokinetic and Pharmacodynamic Evaluation of JL ENDS, Comparator ENDS, Combustible Cigarette, and Nicotine Gum Among Adult Smokers," JUUL Labs Inc. Science Research Library (March 14, 2020).

³¹ Joanna Jay et al., "<u>5-Day Changes in Biomarkers of Exposure among Adult Smokers after Completely Switching from Combustible Cigarettes to a Nicotine-Salt Pod Syste</u>m". Nicotine & Tobacco Research, November 5, 2019.

Peter Hajek et al., "Nicotine delivery and users' reactions to Juul compared with cigarettes and other e-cigarette products," Addiction (2020).

This study found that, of respondents, 50% of these smokers completely transitioned away from cigarettes after six months.³³ At 12 months, transition rates rose to 55%.

The nicotine content of e-liquid is only one factor that influences the amount of nicotine actually delivered by vaping products to the body. For vaping products, actual nicotine delivery is affected by a combination of factors:

- 1. The nicotine concentration of the liquid;
- 2. User behavior (number of puffs taken, volume of puff); and
- 3. The device's characteristics (e.g., heating temperature).

Similar factors have also been cited by the Smokefree Expert Advisory Group of the Health Coalition Aotearoa, New Zealand to demonstrate that nicotine content alone may be an unreliable predictor of nicotine delivery and absorption by the user.³⁴

Limiting nicotine concentration in e-liquids to a low level (e.g., 20 mg/mL as per EU TPD) may not have the intended effect of restricting the amount of nicotine available to users and could have unintended consequences. Studies show that, in lower-strength nicotine products, users tend to engage in behaviors that allow them to obtain sufficient nicotine.³⁵ ³⁶ Users may change their behavior, either by using the product differently, i.e. more often, or by going back to combustible cigarettes.

Users of low-nicotine-concentration vaping products may also attempt to increase the temperature or voltage of their devices, which may lead to more nicotine delivered to the body.³⁷ The promise of vaping devices is based on the idea that they can operate at lower temperatures than burning cigarettes, delivering nicotine while minimizing harmful or potentially harmful chemicals. Increasing the temperature could increase the formation of harmful byproducts that could pose increased risks to users.³⁸ The JUUL device does not permit the user to increase temperature or voltage for this very reason. Many ENDS devices do, however, and in a study, 70% of users who were able to do so increased temperature or voltage when using lower-concentration nicotine e-liquids.³⁹

³³ Christopher Russell, Farhana Haseen, and Neil McKeganey, "Factors associated with past 30-day abstinence from cigarette smoking".

³⁴ Smokefree Expert Advisory Group-Health Coalition Aotearoa, "Summary of the discussion paper on the regulation of Electronic Nicotine Delivery Systems (e-cigarettes, vaping) in Aotearoa New Zealand," (2020).

³⁵ American Association of Poison Control Centers, <u>National Poison Data System Annual Reports</u>, 2018.

³⁶ C Vardavas and P. Behrakis, Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms, Directorate-General for Health and Food Safety, European Commission (Brussels, 2016), 9.

DeVito, E.E., & Krishnan-Sarin, S. (2018). E-cigarettes: Impact of E-Liquid Components and Device Characteristics on Nicotine Exposure. Current Neuropharmacology, 16, 438-459.

Flora, Jason W., et al. "Method for the Determination of Carbonyl Compounds in E-Cigarette Aerosols." Journal of Chromatographic Science, vol. 55, no. 2, 2016, pp. 142–148., doi:10.1093/chromsci/bmw157.

Dawkins, Lynne, et al. "<u>'Real-World' Compensatory Behaviour with Low Nicotine Concentration e-Liquid: Subjective Effects and Nicotine, Acrolein and Formaldehyde Exposure.</u>" Addiction, vol. 113, no. 10, 2018, pp. 1874–1882.

Thank You

We would like to express our thanks to the Health Select Committee and its members for your consideration of our submission. We would also like to acknowledge the work of MOH officials in their careful and considered drafting of the Bill.

We otherwise welcome any questions you may have following the reading of our submission, and look forward to making an oral submission before the Committee if an opportunity is afforded to us.

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