Submission form

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Additional information

I am, or I represent an organisation that is, based in:

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Do you have any commercial interests?

☐ I have a commercial interest in tobacco products

☐ I have a commercial interest in vaping products

☐ I have commercial interests in tobacco and vaping products

☒ I do not have any commercial interests in tobacco or vaping products

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Protection from commercial and other vested interests of the tobacco industry

New Zealand has an obligation under Article 5.3 of the World Health Organisation Framework Convention on Tobacco Control (FCTC) when 'setting and implementing public health policies with respect to tobacco control … to protect these policies from the commercial and other vested interests of the tobacco industry'.

The internationally agreed Guidelines for Implementation of Article 5.3 recommend that parties to the treaty 'should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products'.

The proposals in this discussion document are relevant to the tobacco industry and we expect to receive feedback from companies in this industry. We will consider all feedback when analysing submissions.

To help us meet our obligations under the FCTC and ensure transparency, all respondents are asked to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry.

Please provide details of any tobacco company links or vested interests below.

We have no direct or indirect links with and do not receive funding from the tobacco industry or affiliated organisations and individuals, nor do we have links or indirect links or receive funding from vaping and vaping-related organisations.

Please return this form:

By email to: vaping@health.govt.nz

By post to: Vaping Regulatory Authority, PO Box 5013, Wellington 6140.

Consultation questions

This submission is from University of Otago members of the ASPIRE2025 Research Centre, a partnership between major New Zealand research groups carrying out tobacco control research to help achieve the Government's goal of a tobacco-free Aotearoa by 2025.

Before responding to the specific consultation questions we set out the thinking that has informed our response. We are aware that regulation/legislation for e-cigarettes and related products is highly contested, with many uncertainties due to gaps in the scientific literature and limited experience from, and evaluation of, different potential approaches to regulation.

Members of the ASPIRE 2025 Centre have based our advice and recommendations on what we believe are broadly agreed principles within the tobacco control sector. We have focused our comments on topics where we can offer research expertise and have not commented on topics where we have not conducted research and cannot offer expertise.

The principles we suggest should guide legislation and regulation relating to vaping are those developed by the Smokefree Expert Advisory Group (SEAG) of the Health Coalition Aotearoa, which comprises academics, practitioners and advocates from the smokefree sector who hold diverse views on the role vaping and harm reduction approaches may play in achieving the Smokefree Aotearoa goal.

Smokefree Expert Advisory Group principles

1. *The primary aim of ENDS-related policies should be to support health equity through achieving the Smokefree 2025 goal of minimal smoking prevalence among all population groups in NZ; the policies should not create barriers to achieving a longer term Tupeka Kore goal of eliminating nicotine use as well as tobacco use.*
2. *ENDS-related policy options should be considered and evaluated in the context of the overall policy environment, taking into account complementarity with, and impacts on, other current or potential measures to achieve the Smokefree 2025 goal;*
3. *Smoked tobacco product regulation should always be more stringent than that applied to ENDS because of the greater harm caused by smoked tobacco products;*
4. *ENDS-related policies should aim to:*
    - *(i) maximise the benefits of ENDS (such as supporting smokers to quit smoking; or for those who cannot quit, to transition completely from smoking to ENDS), and*
    - *(ii) minimise harms related to ENDS use. This includes minimising: the health risks that ENDS users are potentially exposed to; the initiation of nicotine-containing ENDS by non-smokers (especially children and young people), and potential 'gateway' effects of ENDS use to smoking.*
5. *Priority should be given to ENDS-related policy and regulation that help reduce smoking among Māori, Pacific peoples, families experiencing higher levels of deprivation, people with mental health conditions, and other groups where smoking prevalence is high.*
6. *The Ministry of Health should continue to monitor emerging evidence on ENDS, particularly their potential impacts on smoking prevalence and users' health in New Zealand.*
7. *Policies and regulations should be crafted so as to be able to be updated swiftly in light of new evidence.*

We believe Principle 1 should guide all policy development. Principles 2 and 3 also have particular relevance to our responses. These principles state first that e-cigarette/vaping product regulation should not be viewed in isolation, but rather should take into account the broader regulatory context for smoked tobacco products. Second, the overall regulatory/policy framework should follow proportionate regulation and always be more stringent for the most hazardous smoked tobacco products compared with less hazardous alternatives such as vaping.

An innovative feature of the New Zealand vaping legislation is the distinction created between specialist and generic vaping retailers. Our comments recognise the important distinction between these retail stores set out in the legislation. This distinction enables differential regulation of these outlets, which we believe could ensure people who smoke receive better support to transition to vaping products (and eventually to cease nicotine use) while affording greater protection to people who do not smoke.

The legislation provides for distinctions in the flavours specialist vape stores and generic retailers may sell but could also be extended to cover the following points:

- Vaping product displays allowed in specialist stores but not in generic retailers (see section 3.1, point 6) and different public information messages about vaping products provided in specialist retailers (harm reduction messages) and generic retailers ("increased risk" messages) (see section 3.4, point 11).
- Additional requirements for staff training in smoking cessation support for specialist stores (see section 3.7, point 17).
- The packaging and on-pack messages required. We recommend all products sold in generic outlets are required to use standardised packaging and feature "increased risk" messages while specialist vape stores may use branded packaging that features "reduced risk" messages (see section 4, point 17).
- More stringent restrictions on maximum nicotine concentrations for vaping products sold in generic stores compared to specialist vaping stores (see section 5.2, point 34).

We also note principles 6 and 7, which call for rigorous monitoring and evaluation of regulatory and policy approaches so their impact on intended and unintended consequences is clear. This monitoring and evaluation should include impacts on equity, and the findings should be used to review regulatory policy and inform any changes required. We note that the track record for evaluating smokefree and vaping-related policy interventions in Aotearoa is weak. Recent interventions such as the ban on point of sale displays of tobacco products (2012), standardised packaging of tobacco products (2018), expansion of smokefree areas by local government (ongoing), and even the vaping legislation introduced in 2020, have not been accompanied by any specific Government funded monitoring or evaluation.

Regulatory proposal 1: Defining an internal area

1. Which option do you support for the definition of an internal area and why?

Based on our extensive experience of research assessing air quality in relation to smoking tobacco products,[1-4] we strongly advise against option D. Under this option measurement and enforcement of regulations based on air quality assessments are likely to be complex to administer, monitor and enforce, and open to challenge. We concur with the Ministry's view that option B has the virtue of being simple to understand and administer, and suggest this should be the preferred option unless very strong arguments are made in support of options A or C.

We note there is an opportunity to provide for a distance measure from all doors and windows (e.g. 10 metres) in which neither smoking nor vaping is allowed, as many North American jurisdictions have required. This approach is likely to give the best protection to workers' and patrons' health and would increase clarity regarding legal requirements.[5]

2. If you support option c, or if option c were to proceed, would you support a 50 percent coverage threshold? If not, what threshold would you suggest and why?

N/A

Regulatory proposal 2: Specialist vape retailer approvals

We recommend the following actions:

- **Introducing a licensing system that includes specialist vape retailers, generic retailers and all tobacco retailers.** The current legislation contravenes principle 3 above as the approval/ registration system applies only to specialist vape retailers and thus is more stringent than requirements of tobacco retailers, despite the fact that tobacco is a more dangerous product. Requiring all sellers of smoked tobacco to obtain a licence and meet specified criteria will be critical to achieving and assessing progress in reducing tobacco supply.

- Allowing regulated product devices to be sold only at specialist vape stores.

- Requiring all retailers of vaping products (whether generic or specialist) to be fit and proper persons (i.e., to have demonstrated knowledge about vaping products and risks), and that this requirement should be a criterion used to assess licensing applications.

- Providing routes for communities to comment on new vape store locations and ensuring that community voices inform licensing decisions. Licensing decisions should also include sensitive site provisions (e.g., retailers of vaping and tobacco products should not be located within 1 km to schools).

- Ensuring the regulations include provisions to remove licences from retailers who sell to minors or are otherwise noncompliant, and that an effective compliance monitoring and enforcement process is implemented.

3. Do you agree that being in a rural location should be a factor in determining whether to approve an application to be a specialist vape retailer with the lower threshold of 60 percent of sales from vaping products?

We support the proposed approach but suggest keeping the threshold levels under review (we suggest every 12 months). Compliance with the 60/70% threshold should be monitored and enforcement action taken as appropriate.

4. Are there any other criteria that should be considered when determining whether to approve an application to be a specialist vape retailer with the lower threshold of 60 percent of sales from vaping products?

At this point, we believe that the current proposal should be implemented, monitored, and evaluated for impact. For example, an evaluation could assess the number of specialist retailers and their distribution in relation to populations (to evaluate how accessible these outlets are to people who smoke, including in more rural areas). People who vape and smoke should be surveyed to assess their source of vaping products, whether they have sufficient access to specialist retailers, and whether they can access support to help them choose and correctly use vaping products to quit smoking or switch completely to vaping. Community views should also be sought and retailers'

(or proposed retailers') proximity to schools should be assessed. Underage access to vape products should also be monitored.

Decisions on whether to change these and other regulations should await the outcome of this evaluation. If evaluation suggests that lack of supply is a problem in some areas due to the absence of specialist retailers, then relaxing the criteria for specialist status in specific regions could be considered. Similarly, if underage access is problematic, then tightening of enforcement and regulations may be needed (e.g., to limit the proximity to schools of vaping retailers to more than 1 km).

We also believe monitoring should be put in place immediately to assess the sale of smoked tobacco products by specialist vaping stores; monitoring should assess the number of specialist vape stores selling smoked tobacco products and record sales on a monthly basis. Research should also be undertaken to assess the impact of supplying both products on smoking prevalence, quit attempts and relapse. For example, it is possible stores that sell both types of product are less likely to encourage and support smoking cessation among dual users (people who vape and smoke) or ex-smokers who relapse from vaping to smoking. Evidence of these problems raises the possibility that it may be necessary to prohibit sales of tobacco products in specialist vaping stores.

5. Do you agree that regulations are not necessary at this stage? If not, what do you propose should be put in regulations?

See previous response.

Regulatory proposal 3: Promotion, information and advice

3.1 Display of vaping products in retail settings

6. Do you agree that the display of vaping products should not be regulated at this stage? If you do not agree, what controls do you think should be put in place and why?

ASPIRE 2025 **does not agree** with the proposal not to regulate the display of vaping products at this stage.

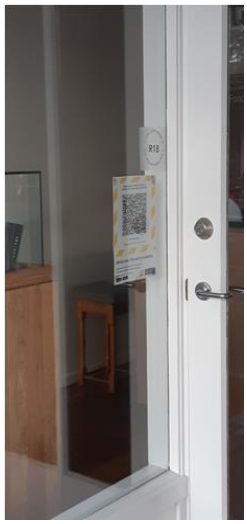
ASPIRE 2025 recommends two key points:

- Regulating the display of vaping products and differentiating between specialist vape stores and generic retailers.
- Requiring all R18 websites to have age-verified entry to the site and age-verified delivery of any products purchased via the site.

We also recommend monitoring compliance and ensuring that enforcement occurs with robust penalties for persistent breaches of the regulatory requirements. We suggest the first breach should be treated using an educative approach (a warning and further information about the regulations). Second (and subsequent) breaches should attract increasing penalties, including revoking licences to sell regulated products.

Regulating the display of vaping products

We strongly support restrictions that require all retailers of vaping products to ensure these products are not visible from outside their store. At present, products may be featured in window displays visible to all passers-by. Vaping stores located on high-traffic streets will thus be displaying these products to people passing by the store, irrespective of their age or smoking status. The photos at right were taken from outside a Dunedin specialist vape store located on the main shopping street. The left photo and the photo below show a display of colourful vaping products in the front window, immediately juxtaposed with the footpath. The photo on the right show the R18 sign is not visually prominent, as it could be if placed in the front window or on the door surface to right.



We do not believe that restricting product visibility would deter people who smoke from entering the store to obtain more information. Rather, this measure would avoid potentially high casual exposure to young non-smokers, reduce the curiosity likely to be aroused by casual exposure, and thus reduce the risk of experimentation.

We note Section 3A 1(b) and (c) state the purpose of the Smokefree Environments and Regulated Products (Vaping) Amendment Act (2020) includes (our emphasis):

(*b) **to prevent the normalisation of vaping**; and*

(c) to regulate and control the marketing, advertising, and promotion of regulated products (whether directly, including through the appearance of regulated products and packages, or through the sponsoring of other products, services, or events) in order to improve public health by—

(i) discouraging people, especially children and young people, from taking up smoking; and

*(ii) **discouraging non-smokers, especially children and young people, from taking up vaping or using smokeless tobacco products**;*

We therefore strongly recommend that vaping products should not be visible from store exteriors. Allowing vaping products to be displayed without restriction is inconsistent with the stated purposes of the Act.

We support the regulation of vaping products display at this stage. We further recommend differentiating between generic retailers and specialist retailers, and between electronic nicotine delivery systems and heated tobacco product systems.

We do not believe that any electronic nicotine delivery systems (ENDS) products or any heated tobacco products (HTPs) should be displayed in generic stores for two main reasons: exposure to non-smokers, particularly children and young people, and the potential normalisation of ENDS or HTP use that could follow.

Most people who visit generic stores will be non-smokers, thus allowing vaping products to be displayed in these stores means many non-smokers, including children and young people, will be exposed to products that they should not use. Current evidence from New Zealand suggests point-of-sale marketing is widespread.[6] Evidence examining exposure to retail displays featuring smoked tobacco products found strong associations between exposure and the risk of experimentation with smoking among New Zealand adolescents;[7] these associations were weakened following the removal of tobacco products from point-of-sale display.[8] It is logical to assume these associations would also be apparent following exposure to vaping products. **We therefore recommend vaping products in generic stores be kept in secure cabinets where they cannot be seen by store customers,** but where a plain sign attached to the cabinet could indicate that ENDS products are available in the store.

Our concern about the display of vaping products within generic retail outlets relates stems in part from a qualitative study of NZ-based generic retailers, who had a poor understanding of the products they sold.[9] While we understand and acknowledge the need to support smokers to transition from combusted tobacco to less harmful nicotine delivery options, such as ENDS, we believe these products should only be sold by people with the expertise to advise their customers. Allowing POS displays in retail outlets where product-specific expertise is not available fails to recognise that the transition from smoking to exclusive ENDS use is not always simple or straightforward;[10-12] retailers who are uninformed about the products they sell risk offering poor advice that jeopardises smokers' quit attempts.

By contrast, people visiting specialist vape stores, which will be R18 outlets, will be much more likely to be people who smoke and who could potentially benefit from switching to ENDS products. Allowing displays in these stores could reach this audience effectively with less exposure to non-smokers. **We therefore agree that vaping product displays should be**

permitted within specialist retailer stores so long as these meet other requirements, such as not being visible to people outside the stores (as currently occurs).

Heated tobacco products (HTPs) are even more ambiguous than vaping products; they are likely to be more harmful than vaping products, it is not clear how effectively they assist people who smoke to quit or switch completely from smoking, or whether (and by how much) they reduce the harm of combusted tobacco products. Analysis of data submitted by Philip Morris International (PMI) in support of its IQOS product concluded (our emphasis added): "Because US law required PMI to provide detailed results of their IQOS research for its MRTP application, it was possible to independently assess their research. **PMI's own data do not support its claims that IQOS is less dangerous than cigarettes**."[13] Furthermore, a second analysis of PMI's data concluded (our emphasis added): "PMI's own data and available evidence from scientific studies conducted independent of the tobacco industry regarding how novel tobacco products are currently being marketed suggest that **introduction of IQOS will result in adolescent and young adult non-users initiating tobacco use with IQOS** and could also increase poly-use of IQOS along with other tobacco products."[14] Analysis of a British American Tobacco presentation to potential investors also revealed their expectation that HTPs would drive profit growth and recruit non-smokers.[15]

The uncertainty about HTPs' benefits, such as reduced harm to health and effectiveness at assisting smokers to quit smoking, and evidence tobacco companies are aggressively marketing these product to younger, non-smoking, audiences, and to Māori, indicates a need for very cautious policy.[14,16,17] **We therefore recommend that sales of HTP products should not be permitted in generic retail outlets and that displays of these products should not be permitted in any retail outlet.**

Past experience suggests regulation of product displays needs to be monitored and, in the event of non-compliance, enforced. Previous research led by ASPIRE 2025 found widespread non-compliance with the regulation of tobacco product displays in the absence of monitoring and enforcement.[18]

3.2 Price lists given to retailers for tobacco only

7. Do you support the proposal to restrict the information allowed on manufacturers' price lists for tobacco products?

Yes; the proposal needs to include all regulated products, including smokeless tobacco products and heated tobacco products.

8. Is there any other information that you consider should be allowed on manufacturers' price lists for tobacco products? If so, what do you propose?

We believe this information should be tightly regulated and do not support allowing information other than the details set out in the consultation document. We do not believe images of any regulated product (smoked tobacco, heated tobacco or ENDS) should be permitted. Recent evidence shows how tobacco companies have used retailers to market products and it is very important that NZ regulations limit the potential for such marketing to occur.[19]

3.3 Public health messages

ASPIRE 2025 recommends the following actions:

- Develop a wider communications strategy that includes campaigns to deter vaping among young people, who are at particular risk of experimenting with vaping products, and promote greater knowledge among retailers, who are likely to be asked to advise on vaping product use.
- Develop a parallel campaign to deter smoking uptake among all population groups, particularly among young people. This approach should be part of a wider strategy that recognises smoking is more harmful than vaping, and that neither are appropriate for people not already dependent on nicotine, particularly young people.
- Develop more nuanced in-store and on-pack messages for vaping and heated tobacco products that recognise the different customers likely to visit generic retailers and specialist vape stores.

9. Do you consider that other information, beyond the information that Vaping Facts already outlines, should be designated as a public health message issued by the Director-General of Health for public services and any publicly funded individuals or organisations to use? If so, what do you propose?

Wider Communications Strategy

The Vaping Facts website has been designed to provide information to people who smoke and has less information to deter uptake among children and young people, or to inform their parents about the risks of vaping. Nor does the site appear to contain information to inform retailers selling vaping products.

We recommend urgent action to denormalise vaping product use among young people, who have been the targets of aggressive marketing.[16] Data from the Youth19 survey of 13-18-year olds (*n*=7,700) found that nearly two-thirds (65%) of students who had ever vaped, and nearly half (48%) of regular (at least monthly) vapers, had **never** smoked cigarettes.[20] Furthermore, data from both the Youth 19 and ASH Year 10 surveys show youth vaping (both ever use and regular use) has increased rapidly.[20,21]

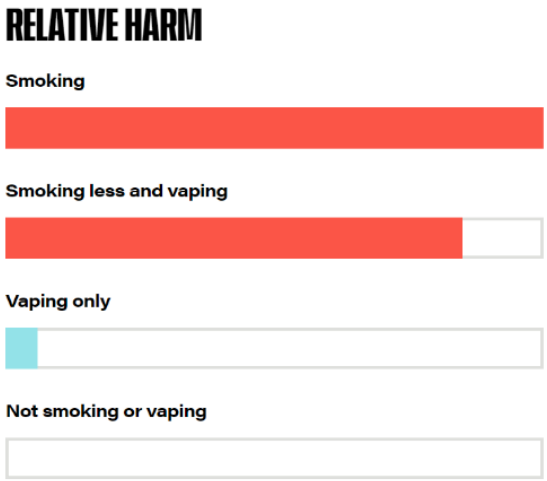
Specifically, we strongly recommend a comprehensive youth-focussed campaign (informed by young people) be initiated to complement the Vaping Facts website and deter ENDS uptake. Information from this campaign should also be available for use in public health messages. The CDC has an excellent website that could be drawn upon to prepare material for parents (see: **https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html** and FDA campaigns could serve as potential starting points for discussions in New Zealand (see: **https://www.fda.gov/tobacco-products/public-health-education/real-cost-campaign**).

Specific information we believe should be incorporated in the Vaping Facts website (or a separate website specifically designed for young people, parents and schools) includes more details about the risks of nicotine use and subsequent addiction,[22,23] and some discussion of the evidence that ENDS use may be associated with an increased risk of smoking among young people.[24] **We also recommend further campaigns to deter smoking among young people.**

In the absence of information designed to deter youth uptake, some health groups have developed materials to inform parents and young people of the risks of vaping (e.g., see

website developed by the Asthma and Respiratory Foundation here: https://dontgetsuckedin.co.nz/). **We recommend discussing these resources with the site owners with a view to designating these as public health messages**.

We recommend regular updating of the Vaping Facts website to incorporate new evidence about the impact of vaping. We note a recent NZ analysis that collated evidence from biomarkers studies concluded that the relatively safety of ENDS may be considerably less than 95%;[25]a graph currently used on the Vaping Facts website appears to rely on this claim (see relative difference between smoking and vaping). We are concerned the comparison between vaping and non-smoking may suggest that vaping carries only a small risk relative to not smoking, and that this interpretation will not dissuade young people from experimenting with vaping.



Source: https://vapingfacts.health.nz/vaping-vs-smoking/

Given the highly variable and sometimes inadequate knowledge among small retailers of vaping devices and correct use of these,[9] **we recommend developing a website to provide resources to retailers**. This website could provide information that is tested to ensure satisfactory knowledge among retailers wishing to sell vaping products, which should constitute one of the criteria used to assess retailers applying for a licence to sell vaping products.

3.4 Vaping product information in retail settings

10. Do you support limiting information about vaping products in retail premises and on retailers' websites to written authorised statements (other than permitted oral communications)? If not, what do you propose?

Yes.

11. Do you support the proposed statements? If not, what do you propose?

We support use of "harm reduction" messages (targeted at people who smoke and communicating that vaping is very likely less harmful than smoking) but believe these messages should be complemented by "increased risk" messages (targeted at non-smokers and advising that vaping is not harmless and carries health risks and the risk of addiction). **We recommend that specialist retailers should be able to feature the harm reduction messages provided but that generic retailers should be required to feature "increased risk" messages.** This approach would recognise that most people entering a specialist vape store are aged 18+ and that smokers could benefit if they made a complete transition from smoking to ENDS use. However, it would also recognise that most people entering generic retail outlets do not smoke (many are children or adolescents) and so could be at risk if they were to begin using ENDS.

We believe that all retailers who sell vaping products should be required to advise customers they should make a full transition from smoking to vaping, and aim to quit vaping when they feel they are not at risk of relapsing to smoking. Information provided to people hoping to switch from smoking to ENDS use should make it clear that quitting both smoking and vaping would bring the greatest health benefits. All stores selling vaping and tobacco products should also be required to have and display information about local services that can support quitting smoking.

We reiterate the point made in section 3.1, namely that monitoring and enforcement are required to assess compliance with the display of vaping product information.

12. Do you support limiting the format of these notices so that they are consistent with tobacco product notices? If not, what do you propose?

Yes

3.5 Product availability notices in retail premises

13. Do you support the proposal to align availability notices for vaping products with those for tobacco products? If not, what do you propose?

Yes

3.6 Point-of-sale information on purchase age

14. Do you agree there should be a requirement for retailers to display purchase age (R18) notices at each point-of-sale? If not, why not?

Yes

15. Do you support the proposed wording and presentation requirements? If not, what do you propose?

Yes.

As noted in our response to Q6, **ASPIRE 2025 recommends that all online purchase sites should require age verification at the point of order and on delivery**. This dual process would improve the current process (where age requirements are easily circumvented) and reduce youth access to products online.

Because of the rapid increase in youth vaping, we strongly recommend increased monitoring of generic retailers and online purchase sites, and regular monitoring of specialist vape stores, to ensure sales of ENDS products are not being made to those aged under 18. Increased monitoring of generic stores would also enable the Ministry to review oral communications and determine whether these fall within the categories set out in Section 27(3) of the Act. Monitoring should review where people aged under 18 obtain vaping and smoked tobacco products so that the regulations may be modified to reduce access to these supply sources.

We believe other messages would be more effective in communicating the risks of vaping to young people than the proposed message "Vaping products may contain nicotine, which is a highly addictive substance". We have outlined other messages in our response to Section 4 (question 17).

We reiterate the point made in section 3.1, namely that monitoring and enforcement are required to assess compliance with the display of vaping product information.

3.7 Suitably qualified health workers

16. Do you agree that no additional category of person should be added to the definition of 'suitably qualified health worker'? If you do not agree, which category do you think should be added and why?

Yes.

We interpret section 3.7 (p19) of the proposal for regulations to mean that a manager or staff member working in a specialist vape store who completed the Stop Smoking Practitioners Programme would be designated as a 'suitably qualified health worker' who could give advice on transitioning from smoking to vaping. Assuming that interpretation is correct, we support not adding a further category to the definition.

However, we believe a criterion for classification as a specialist vape store should require at least one staff member to have completed a Stop Smoking Practitioners Programme. We note this criterion may require adaptation of the Stop Smoking training to correspond to the role people in specialist stores will fulfil (i.e., they are likely to be focusing on stopping smoking by switching to vaping). Resource implications (i.e., costs of training and where these should fall) will need consideration (unless training is done via an online course).

Consideration will also need to be given to the inherent conflict of interest that specialist vape store staff will have, particularly given that people should be encouraged to switch completely to vaping, and then aim to cease using all nicotine products (a goal that is at odds with the commercial imperative of vape stores).

In addition, we believe all staff working in specialist vape stores should have a basic training in smoking cessation; this training would enable them to respond to queries about where smoking and quitting support is available. Specialist vape stores should also have available information about the location of local cessation support facilities and details of how to access the Quitline. Ideally, people visiting specialist vape stores to quit smoking should enrol with local cessation support services to ensure they receive disinterested advice and support to quit all nicotine use.

Regulatory proposal 4: Packaging

We recommend several changes to the proposed packaging regulations. **We recommend that packaging requirements differentiate between generic retailers and specialist vape stores and recognise the different audiences of each store.** Specifically, we recommend:

- Using more diverse messages than those in the consultation document. Please see our recommendations under Regulatory proposal 3, where we suggest how on-pack design and messaging could reflect the differentiation between generic retail outlets and specialist vape stores provided for in the legislation.
- Using best-practice from smoked tobacco labelling designs with respect to the location and format of warning labels.

17. Do you support the proposed wording of the health warning for vaping products? If not, what do you propose?

We recommend that more diverse messages be used to encourage smokers to switch to vaping and deter non-smokers from beginning to vape.

Our recent work suggests that the message "This product contains nicotine, which is a highly addictive substance" is less persuasive to smokers than "reduced risk" messages. It is also generally less dissuasive to non-smokers than "increased risk" messages.[26]

We found that even "reduced risk" messages could decrease preference for vaping products (relative to no message), though more work is required to test how "reduced risk" messages function when supported by a social marketing campaign. Further work is also required to ensure the messaging is well-understood as requiring a **complete transition** from smoking to vaping. Bearing these caveats in mind, a sub-group of smokers within our study responded well to the following messages:

- If you are a smoker, vaping reduces harms to your health.
- If you are a smoker, vaping reduces your risk of lung disease.

Among people who did not smoke, the proposed addiction message was off-putting, but not as dissuasive as the following messages (based on conclusions 5.1 (conclusive evidence) and 11.4 (moderate evidence) in the NASEM report[27]:

- If you are a non-smoker, vaping increases harms to your health.
- If you are a non-smoker, vaping increases your risk of lung disease.

We recommend that, if the addiction message is used, that it is also accompanied by increased and reduced risk messaging (depending on the target audience). Specifically, **we recommend that all products sold in generic retail stores feature the addiction warning and increased risk messages. We further recommend that products sold in specialist vape stores feature reduced risk messages.**

In the example of the proposed packaging the warning appears in the bottom third of the package (p20, consultation document). **We recommend the message should feature on the top third of the exterior packaging** as research undertaken prior to standardised packaging of smoked tobacco products found that the bottom of the package had less visual salience than the top half or middle of the packaging.[28]

We also recommend that warning / information messages be printed on e-liquid bottles. Unlike tobacco packages, where on-pack messages will be viewed multiple times a day because the pack retains high utility (as a container for cigarettes), the external packaging of e-liquid bottles will almost certainly be discarded. Printing messages on **both** the external

packaging and the bottle packaging will ensure the messages continue to have potentially high exposure.

We recommend that all packaging contains the Quitline phone number and website URL.

We recommend that all regulated products sold by generic retailers should be required to use plain or standardised packaging. This recommendation follows the rationale set out above, namely that people visiting generic retailers will be predominantly non-smokers, for whom use of any regulated product will increase the health risks they face.

18. Do you agree with the proposed requirements for the health warning panel for vaping products? If not, what do you propose?

    Please see our response to Q17.

19. Do you support the proposed wording of the health warning for smokeless tobacco products? If not, what do you propose?

    Yes. In addition to the wording proposed, we suggest a way for consumers to report any adverse effects from using the product, including a phone number and/or email address for the relevant authority.

20. Do you agree with the proposed requirements for the health warning panel for smokeless tobacco products? If not, what do you propose?

    We tentatively support the proposed health warning panel "This product damages your health and is addictive" (and te reo translation) but would like clarification that this message has been tested empirically in New Zealand or follows best international practice. We note that the words "damages your health" lack specificity – and suggest consideration of wording around cancer.

21. Do you agree with the proposals for product presentation for vaping products? If not, what do you propose?

    Yes

22. Do you agree with the safety messaging statements? If not, what changes to them do you suggest?

    We support the requirements regarding safety messaging.

23. Do you agree with the proposals for product presentation for smokeless tobacco products? If not, what do you propose?

    We recommend that smokeless tobacco products, like combusted tobacco products, should be required to use standardised packaging. Standardised packaging has reduced the

appeal of tobacco packaging to young people;[29] given young people are predominantly non-smokers, packaging should be designed to deter uptake among this group.

24. How much time do you think smokeless tobacco product manufacturers should have before they need to comply with new packaging requirements? Please give reasons.

No longer than six months. A short transition period reduces opportunities to innovate with pack design, as occurred before the introduction of standardised packaging for smoked tobacco products.[30]

25. Do you agree with the proposed instructions on and in the packaging? If not, what changes to them do you suggest?

We do not believe the packaging should contain information about correct use or handling; this information effectively markets the product to users. We believe only the consequences of incorrect use should appear on smokeless tobacco products. We also recommend that all smokeless tobacco products are required to display the Quitline phone number and website.

26. Do you agree with allowing track and trace markings? If not, why not?

Given evidence that tobacco companies have been complicit in illegal trade of tobacco products,[31] **we recommend that the only track and trace markings permitted are those prepared by the Ministry of Health (or another NZ Government agency).**

27. Do you support the proposal to restrict the quantity of smokeless tobacco sticks in a package to 20 or 25? If not, what do you propose?

Yes.

28. How much time do you think manufacturers of vaping products and smokeless tobacco products should have before they need to comply with new packaging requirements? Please give reasons.

See our response to Q24.

We again reiterate the need for monitoring to assess the impact of messages and packaging on key groups, including people who smoke and non-smokers (especially young people). We recommend monitoring experimentation and regular use among non-smokers, reasons for use and usage cessation, and the impact of other packaging elements.

Regulatory proposal 5: Product notification and safety

5.1 Product notification requirements

29. Do you agree that these are the right details for the Ministry of Health to collect for each notifier? If not, what changes would you make to the details collected?

Yes

30. Do you agree that the notifier should declare that they meet the current requirements of the Act? If not, what approach to enforcing the provisions of the Act do you suggest?

Yes

31. Do you agree that these are the right details for the Ministry of Health to collect for each notifiable product? If not, what changes would you make to the details collected?

Yes

32. Do you agree that the notifier should declare that each product meets the current requirements of the Act? If not, what approach to enforcing the provisions of the Act do you suggest?

Yes

5.2 Product safety requirements

33. Do you agree with our approach of basing product safety requirements on the EU and UK legislation and guidance? If not, what approach to our product safety requirements do you suggest we use?

We support basing product safety requirements on the EU legislation and guidance. If the UK guidance has been changed following Brexit, we would need to see details of the changes before agreeing with these.

34. Do you agree with the product controls we are proposing to include in the product safety requirements? If not, what changes to the areas that the product safety requirements cover do you suggest?

We recommend one major change to the proposed product safety requirements. We recommend that restrictions on the maximum nicotine concentration of vaping products are strengthened with a 20mg/ml restriction for all products sold in generic stores, and a

20mg/ml limit for e-liquids but a higher 50mg/ml limit for nicotine salt-based products at R18 specialist stores.

We do not have topic expertise on many of the proposed areas of product safety, so have not commented on these proposals, other than to state that they appear to be reasonable. **We strongly recommend that monitoring is in place to identify and allow prompt corrective action in the event that actual or potential adverse impacts of vaping products emerge.** A monitoring system should include an 'early warning system' (similar to the Yellow Card system in the UK) to ensure rare but severe adverse events are recognised promptly.

We note the proposal to limit e-liquid nicotine levels to 20mg/ml, but nicotine salts to 50mg/ml. The proposed NZ product safety regulations are described as being largely based on EU and UK legislation and guidance; however, that is not the case for nicotine limits for nicotine salts, as the relevant limit in the UK and EU is 20mg/ml for all vaping products. This discrepancy is not explained in the proposal document.

The presumed goal of regulation is to limit the nicotine delivery (and hence addictiveness of vaping products) and reduce the risk that non-smokers (particularly youth) find these products appealing and become addicted long-term users. Limiting nicotine delivery will also assist people who smoke and who switch to these products to later stop vaping and cease using nicotine-delivering products.

However, there is a potential tension between ensuring that the permitted nicotine concentrations are high enough to make vaping products 'satisfying' and effective at reducing cravings among people who switch to them from smoking, while also minimising their appeal (e.g. the 'buzz' from vaping) and addictiveness to never-smokers, particularly youth.

An additional complication is that the addictiveness, ability to assuage cravings, and degree of satisfaction from vaping products will depend not only on the concentration of the nicotine in the e-liquid or pod/capsule, but also on the nicotine product used. For example, the availability of nicotine is greater in the nicotine salt form than in the free-base form found in e-liquids. Furthermore, concentrations will vary by device; for example, higher voltage tank devices can release more nicotine than can low voltage 'pod' style devices. This difference is a reason why the latter devices use e-liquids with high nicotine concentration (e.g. 50 mg/ml or more in the US where regulations allow it) typically in the form of more bioavailable nicotine-salt based solutions, while tank devices typically use lower concentrations of the less bioavailable nicotine in free-base e-liquids.

Concerns were raised in response to a rapid increase in youth use of high nicotine concentration pod devices in North America from 2017-19, and subsequent proliferation of these products.[32] [33] As noted above, the main potential advantage of restricting nicotine content is to minimise appeal and addictiveness of vaping products to never-smokers, particularly youth. Some evidence suggests strict nicotine concentration restrictions can be effective in this regard, as shown in comparisons of youth uptake and regular vape use in jurisdictions with and without nicotine concentration limits. In the UK, for example, a limit of 20mg/ml applies to all vaping products, including nicotine salts. The UK has been relatively successful at limiting the use of vaping products among youth (5% last monthly vaping among 11-18 year olds in the ASH-Y 2020 survey). [34] However, by contrast, from 2017-19 Canada and the USA experienced rapid increases in regular use of vaping products (particularly JUUL devices) by high school students that were much more pronounced than those seen in the UK. [35,36]

Differences in the US and Canadian contexts (compared to the UK) included lack of nicotine concentration limits, wider availability of new Pod devices (particularly JUUL) that proved highly appealing to youth, and unrestrained youth-oriented marketing. These differences seem likely to have resulted in the greater increase in youth vaping in North America. However, the degree to which the differences in nicotine concentration regulation contributed to the differences in youth vaping is difficult to determine. Nonetheless,

influenced by these findings, Health Canada is currently proposing to introduce a limit of 20mg/ml nicotine concentration for all vaping products.

The major potential drawback of strict nicotine limits is that they may result in vaping products being less effective in supporting people who smoke to switch away from smoking. They could also encourage compensatory behaviours such as more intense or frequent puffing that results in greater e-liquid consumption and thus greater exposure to any toxins generated through vaping.[37,38] Conversely, having a higher upper limit for the concentration of nicotine will ensure the availability of higher strength nicotine vaping products, which may be more effective in helping smokers (particularly heavily addicted smokers) to switch from smoking and eventually quit nicotine use, and may reduce puffing frequency and thus consumption of e-liquids and exposure to toxins.

The evidence about whether higher nicotine strength products are more effective at helping smokers to switch away from smoking is currently unclear, although it is plausible. For example, a randomised study found that higher strength pod device products were rated similarly to usual cigarettes and better than lower strength pod products at relieving cravings and in perceived nicotine delivery, though not in satisfaction.[39] Experimental studies with small numbers of volunteers have also demonstrated promising results (for nicotine delivery, relief of cravings and user satisfaction) for high nicotine concentration JUUL products compared to lower strength JUUL products, other vaping products and cigarettes.[40,41] An observational (non-randomised uncontrolled) studies reported at this year's Society for Nicotine and Tobacco Research conference showed promising results for the rate of switching after one year with high strength pod style products.[42 43] An observational study compared rates of switching among matched users in North America who had access to high strength (59mg/ml) nicotine products and users in the UK who were only able to legally access 20mg/ml products and found greater switching at six months follow-up among the North American participants.[44] However, these studies had methodological weaknesses and were conducted using JUUL products and funded by JUUL systems, creating a potential conflict of interest.

We believe the regulations could use the distinction between specialist and non-specialist stores to balance the tension between ensuring smokers have access to products that are adequate substitutes for smoking while minimising young people's access to high concentration nicotine products. A two tier system could involve a proposed limit of 20mg/ml of nicotine for e-liquids in all stores (in line with EU, UK and Canadian approaches) but allow up to 50mg/ml for nicotine salt based products that applies to products sold at specialist stores only, while nicotine salts products sold in generic retail outlets would have a 20mg/ml limit.

As with other measures, it will be important to ensure that a comprehensive monitoring and evaluation framework is in place to assess the use of and source of supply of different types of nicotine products, including strength of nicotine e-liquids and salts, among smokers and non-smokers, particularly among youth. This approach would also require a robust system for monitoring and enforcing compliance with the ban on underage sales of the high strength nicotine salt products in specialist stores.

Finally, we note that introducing limits to the strength of nicotine-containing vaping products will create a further anomaly in which vaping products are more rigorously regulated than smoked tobacco products (as smoked tobacco products have no limits on their nicotine content), which is the inverse of proportionate regulation. **We therefore strongly recommend that the restrictions on nicotine concentrations on vaping products are accompanied by a clear commitment to introduce mandated very low nicotine cigarettes in a very short timescale to reduce their addictiveness and increase the appeal of vaping products as substitutes to smokers who cannot or do not wish to quit using nicotine products**. **We also strongly recommend that more stringent restrictions are**

introduced on the availability of smoked tobacco products so as to make them less easily available than all types of vaping products.

35. After reviewing our full proposal in Appendix A, do you agree with our proposed product safety requirements? If not, what changes to them do you suggest?

Yes

Regulatory proposal 6: Annual reporting and returns

36. Do you support the proposals for manufacturers' and importers' annual sales reports? If not, what do you propose?

Yes

37. Do you support the proposals for specialist vape retailers' annual sales reports? If not, what do you propose?

Yes, but we also strongly recommend generic retailers also be required to provide annual sales reports. We note that it is a major anomaly that annual sales reports will be required for vaping products and not for much more harmful smoked tobacco products. We suggest correcting this anomaly is essential and that all retailers who sell vaping or tobacco products should be licensed and required to provide annual sales returns reports for both product types.

Regulatory proposal 7: Fees

38. Do you agree the Ministry of Health should charge for the activities identified? If not, what activities do you suggest we charge for?

Yes

39. Do you agree with the way the fees are structured? If not, how should they be structured?

Yes, but we note that the impact of the fees (intended and unintended) needs to be monitored and modifications made as necessary.

40. Do you agree with the level of each of the fees? If not, how much do you suggest the Ministry of Health should charge?

Yes, but we note that the impact of the fees (intended and unintended) needs to be monitored and modifications made as necessary

41. Do you agree with our assumptions on annual volumes of work? If not, what assumptions do you suggest we use?

Yes

42. How many products do you anticipate notifying yourself?

None

43. Are there additional issues relating to fees and charges that you would like us to consider?

No

44. Do you agree that we should reduce fees for very low-volume products? If not, how would you suggest the Ministry of Health handles very low-volume products?

No – suggest a flat rate fee structure is tried in the first instance.

45. How would you suggest we define very low-volume products?

N/A

46. Do you have suggestions for the design of any provisions, including suggestions for: (a) limits on the number of products that any notifier can have fee exemptions for (b) administrative efficiency (c) any other issues that might be associated with low-volume products?

No

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