The Paediatric Society of New Zealand
Te Kāhui Mātai Arotamariki o Aotearoa

Vaping Regulatory Authority
133 Molesworth Street
vaping@health.govt.nz

To the consultation committee re: the Smokefree Environments Regulated Products Act 1990: Regulatory Proposals

Background in relation to our submission re the Regulatory Proposals

The Paediatric Society of New Zealand represents paediatricians and paediatric health care workers from around New Zealand. Our principal advocacy role is in regards to the health and well-being of children and young people.

Our opinion is based on the following background.

1. E-cigarettes were invented in 2003, and available in NZ since 2006, although uptake has only been significant in the last 5-10 years. This means that research on health effects (side effects and comparisons with tobacco) is still in its infancy, compared to tobacco health research, which dates from the 1950's. Tobacco health research took a long time to become established and well-accepted, partly owing to obstruction or obfuscation of research by the industry. Our knowledge of health effects, for instance in pregnancy and pre-conceptionally, is still developing 70 years later.

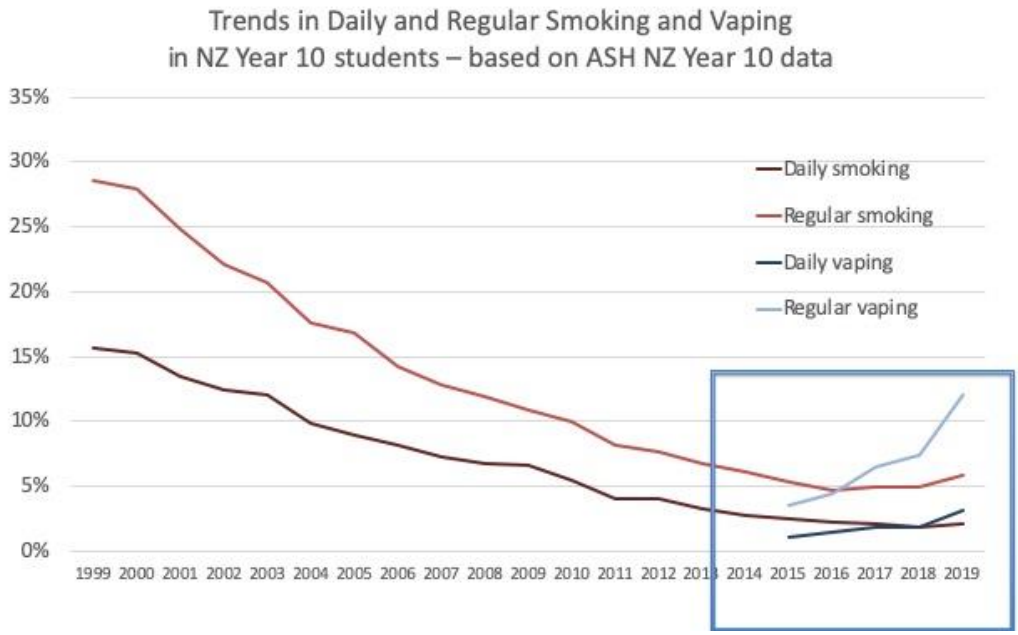
2. E-cigarette health research is complicated enormously by the number of products, delivery systems, flavours (>8,000) and additives, which means that population measures of health effects, stratified by these factors will be a laborious process.

3. On the other hand, tissue and cellular research (reviewed in Chun LF et al. Pulmonary toxicity of e-cigarettes. Am J Physiol Lung Cell Mol Physiol. 2017 Aug 1;313(2):L193–L206, and Overbeek et al. A review of toxic effects of electronic cigarettes/vaping in adolescents and young adults. Crit Rev Toxicol. 2020 Jul;50(6):531–8.) clearly supports that exposure to vape aerosol is potentially harmful, and often in the same ways as tobacco exposure. All international respiratory societies have registered major concerns about the potential long-term harms of e-cigarette use (*Forum of International Respiratory Societies:* Ferkol TW, et al. Electronic cigarette use in youths: a position statement of the Forum of International Respiratory Societies. European Respiratory Journal. 2018 May;51(5):1800278. *European Respiratory Society*: Bals et al. Electronic cigarettes: a task force report from the European Respiratory Society. European Respiratory Journal. 2019 Feb;53(2):1801151; *Thoracic Society of Australia and NZ*: McDonald CF et al. Electronic cigarettes: A position statement from the Thoracic Society of Australia and New Zealand. Respirology. 2020 Jul 26;25:1082–9.)

4. The NZ study (Bullen C et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. The Lancet. 2013;382(9905):1629–37) which remains one of the best regarding the benefits of e-cigarettes over traditional NRT products in quitting tobacco smoking show only small benefits, which are partly overshadowed by the fact that people switching to e-cigarettes were far more likely to be continuing to vape after 1 year than those who quit using NRT were to remain on NRT. The size of the benefit seen is very unlikely to improve the likelihood of NZ reaching a Smokefree Aotearoa by 2025.

5. Section 4. above, implies that the only justification for advocating wider availability of e-cigarettes for smokers is harm reduction, and yet the proof that they reduce long-term harm remains theoretical and untested (points 1-3). The European Respiratory Society has rejected harm reduction as a strategy (Pisinger C et al. ERS and tobacco harm reduction. European Respiratory Journal. 2019 Dec;54(6):1902009.)

6. New Zealand data shows that young people are increasingly trying vaping products, and that this trend has been contemporaneous with a slowing and even reversal of previous downward trends in young people smoking. (See attached graph based on ASH NZ data). Young people will continue to emulate adults, regardless of age restrictions, and can readily find adults to access their vapes for them



7. The tobacco industry, whose products now dominate the vaping market, has actively embraced the harm reduction strategy (see BAT's website on harm reduction, as referenced in the current BAT NZ website: https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DO9P3DZW). There is evidence of an industry-led strategy to use e-cigarette marketing and harm reduction as a means "to sustain, rather than replace, cigarette sales, and to increase their influence and credibility with respect to NNDS policy and regulation" (quoted from: Mathers A, Hawkins B, Lee K. Transnational Tobacco Companies and New Nicotine Delivery Systems. American Journal of Public Health. 2019 Feb;109(2):227–35).
Given the multiplicity and deviousness of tobacco industry strategies for circumventing previous regulations worldwide, this means that the government must be vigilant in ensuring that vaping regulations do not provide a foothold for a new phase of tobacco marketing to young people.

Our general position, is:

A. that we accept the move to encourage smokers to quit smoking, including the use of vaping as a nicotine replacement product, but that the aim must be to quit vaping and smoking entirely, not just replace.

B. In this process, we urge that government do everything practical to prevent a future epidemic of adverse events (currently this is a potential but unpredictable risk) due to

young people who would not have smoked becoming dependent on vaping. This is, after all, how the current smoking epidemic is maintained. The stakes are high. It would be a tragedy if the government averted one population health problem only to foster another unforeseen one, a sequence that is not without historical precedent in the world at large.

Thank you for noting this background.

Yours sincerely

Nicola Austin
President

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Submission form

Your details

This submission was completed by: *(name)* Philip Pattemore, MD FRACP

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Organisation *(if applicable)*: Paediatric Society of New Zealand

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Role *(if applicable)*: Click or tap here to enter text.

Additional information

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

☒ New Zealand ☐ Australia ☐ Other *(please specify)*: Click or tap here to enter text.

I am, or I represent, a: *(tick all that apply)*

- ☐ Overseas manufacturer
- ☐ Importer
- ☐ Retailer
- ☐ Wholesaler or distributor
- ☐ Member of the public
- ☐ Other *(please specify)*: Click or tap here to enter text.
- ☐ New Zealand-based manufacturer
- ☐ Exporter
- ☐ Government
- ☐ Institution (eg, university, hospital)
- ☒ Non-governmental organisation

Privacy

We intend to publish the submissions from this consultation, but **we will only publish your submission if you give permission**. We will remove personal details such as contact details and the names of individuals.

If you do not want your submission published on the Ministry's website, please tick this box:

☐ Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act (even if it hasn't been published). If you want your personal details removed from your submission, please tick this box:

☐ Remove my personal details from responses to Official Information Act requests.

Commercial interests

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

Commercially sensitive information

We will redact commercially sensitive information before publishing submissions or releasing them under the Official Information Act.

If your submission contains commercially sensitive information, please tick this box:

☐ This submission contains commercially sensitive information.

If so, please let us know where.

Click or tap here to enter text.

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.

NIL

Please return this form:

By email to: vaping@health.govt.nz

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

Consultation questions

The Ministry of Health is seeking comments on the following.

Regulatory proposal 1: Defining and internal area

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

b

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?

Click or tap here to enter text.

Regulatory proposal 2: Specialist vape retailer approvals

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?

No opinion, except that whichever option is chosen, people in a rural location should not be disadvantaged from other people in terms of increased exposure to marketing, or availability of smoking cessation services.

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?

We submit that the definition of a Specialist vape retailer should include, that in order to apply for a license, a retailer should have completed the Stop Smoking Practitioners' Programme. The definition of a vaping premise should include that an individual who has completed the Stop Smoking Practioners' Programme should be on site to provide supervision

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

We submit that the above requirements should be met

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?

Do not agree We submit that, just as with smoked tobacco products, it is vital to prevent the display or the pricelist becoming a marketing or advertising tool. Adults who want to explore vaping should have no problem locating a vaping store without product displays. It is essential to avoid co-displays of vaping products with confectionery, particularly if the latter are designed to attract children or young people. Although this may not be a common practice currently, we feel it should be legislated to prevent exploitation of a loophole.

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

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?

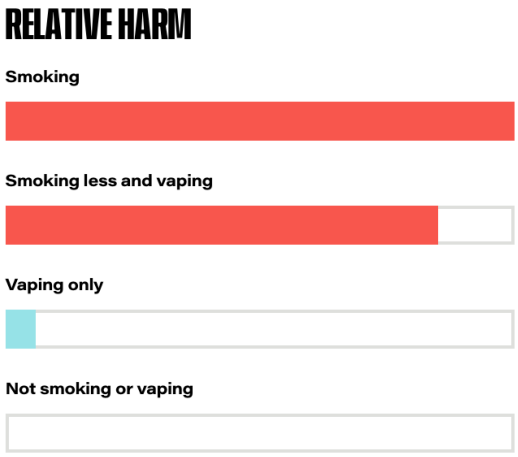
In regards to the last paragraph of this section, the restrictions on tobacco retail pricelists are to prevent pricelists being used as an advertising tool. We believe the same restrictions should apply to vaping product pricelists. These are usually tobacco-derived products, and most commonly marketed by tobacco companies.

3.3 Public health messages

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?

Regarding the Vaping Facts website we take issue with the section Vaping vs. Smoking where the following graph is displayed:



This perpetuates a myth, rather than "fact" that vaping is "95% safer than smoking" which is based on no evidence, and was based only on a straw poll of self-selected "experts" (*The original article was* Nutt DJ et al. Estimating the harms of nicotine-containing products using the MCDA approach. Eur Addict Res. 2014;20(5):218–25., *see two of many rebuttals* Burrowes KS et al. Human lungs are created to breathe clean air: the questionable quantification of vaping safety "95% less harmful". N Z Med J. 2020 Jun 26;133(1517):100–6. *and* Eissenberg T et al. Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes. American Journal of Public Health. 2020 Feb;110(2):161–2). We will not know the size of that "Vaping only" bar for many, many years. We do not believe the Ministry of Health, in a desire to encourage smokers to transfer to vaping, should do so with graphical or other information that gives the impression of certainty, but is not founded on evidence, and may turn out to be false. (If a similar poll had been taken in 1940 among physicians, they are likely to have estimated the harm of tobacco as small).

Aside from this particular issue, we are more interested in the converse question – will funded public health officials be prohibited from giving what they feel is an important public health message even if it disagrees with the Vaping Facts website? Information changes, and there should be freedom of speech to raise concerns publicly. We seek reassurance that this does not amount to a gagging clause.

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?

Not as written. As indicated in our background letter and under Regulatory Proposal 3.3 above, we believe this message should be very carefully worded, because no expert, nor the Ministry of Health, has sufficient evidence to grade the degree of harm or harm reduction from e-cigarettes. The evidence is just not there. Yes, many of the harmful products in smoked tobacco are not present in vaping aerosol, but other products, still untested in the airways and lungs, have been added to vaping aerosol. **If you subtract partly known risks, and then add unknown risks you are left with an unknown risk**.

In any medical product that is beneficial for a condition, some people will suffer serious adverse effects. Any statement therefore that implies that vaping **is** "much less" harmful risks becoming a hostage to fortune. Could a future sufferer sue the retailer, or the government, for providing false reassurance? We propose that the most that can be said at this point, is that

"Switching completely from smoking to vaping *is likely* to reduce harms to your health."

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, given that these are in the main, tobacco-derived products and marketed by tobacco companies

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, given that these are in the main, tobacco-derived products and marketed by tobacco companies

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?

"Vaping products are intended to help quite smoking"

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?

We submit that Supervision should be direct and on site.

Regulatory proposal 4: Packaging

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

We agree, but also suggest that, as with other tobacco-derived products, a variety of warning labels may be helpful, with other labels indicating the uncertainty regarding long term safety of vaping.

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

Yes

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

Labelling of all vaping products, not just those that containe nicotine, should include one of a variety of health notices such as "vaping may damage your lungs" and "vaping products include chemicals which may be toxic"

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

Yes

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

We believe that any product presentation can act as a marketing or advertising tool, as has been well documented for tobacco products. This is not boot polish or hand soap, but a product potentially addictive and harmful to young people. Plain packaging is as essential as for tobacco products, because these are largely tobacco-derived products, and the tobacco industry dominates the marketing.

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

Yes

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

Yes

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.

Within 6 -12 months – we need to arrest the current burgeoning use of vaping products among young people.

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

Yes

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

Yes

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.

6-12 months – as above

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?

Yes

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?

Yes

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

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

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?

Having low cost as a key aspect of the scheme design is not appropriate. The goal should be "reasonable cost"

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?

We submit that reduced fees for low volume products are not appropriate as these products may still be harmful or toxic but with less chance of notification due to low volume

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

No opinion

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 opinion