

Policy Options for the Regulation of Electronic Cigarettes

Consultation submission

Your details

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(Tick one box only in this section)

Are you submitting this:

- as an individual or individuals (not on behalf of an organisation)?
 on behalf of a group, organisation(s) or business?

(You may tick more than one box in this section)

Please indicate which sector(s) your submission represents:

- Commercial interests, including E-cigarette manufacturer, importer, distributor and/or retailer
 Tobacco control non-government organisation
 Academic/research
 Cessation support service provider
 Health professional
 Māori provider
 Pacific provider
 Other sector(s) (please specify): Health Promotion, Supportive Care, Advocacy, Research, Education

(You may tick more than one box in this section)

Please indicate your E-cigarette use status:

- I am using nicotine E-cigarettes.
 I am using nicotine-free E-cigarettes.
 I currently smoke as well as use E-cigarettes.
 I am not an E-cigarette user.

I have tried E-cigarettes.

Privacy

We intend to publish all submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

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Do not publish this submission.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. 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.

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

This submission contains commercially sensitive information.

Declaration of tobacco industry links or vested interest

As a party to the global tobacco control treaty, the World Health Organization Framework Convention on Tobacco Control, New Zealand has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To help meet this obligation, the Ministry of Health asks all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. The Ministry will still carefully consider responses from the tobacco industry, and from respondents with links to the tobacco industry, alongside all other submissions. Please provide details of any tobacco company links or vested interests below.

The Cancer Society of New Zealand does not have any direct or indirect links to, does not receive funding from, nor has any vested interests in, the Tobacco industry.

Please return this form by email to:

ecigarettes@moh.govt.nz by 5 pm, Monday 12 September 2016.

If you are sending your submission in PDF format, please also send us the Word document.

Consultation questions

Although this form provides blank spaces for your answers to questions, there is no limit to the length of your responses; you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

Q1 Do you agree that the sale and supply of nicotine E-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

Yes No

Reasons/additional comments:

Policy Intent

The consultation document indicates that a decision to introduce E-cigarettes into New Zealand has been made, and this consultation is to inform the best mix of legislation and regulation to maximise benefit and minimise harm.

What is not so clear is the policy intention, or what is wanting to be achieved by the new policy direction? Is the intent to support cessation of smoked tobacco, to ultimately replace the use of traditional cigarettes with E-cigarettes, or a combination of both?

The wording in the consultation indicates replacing traditional smoked tobacco with E-cigarettes as the major policy driver.

*The risks and benefits of E-cigarettes are uncertain. There is a lack of clarity about long-term health risks to users and the potential adverse effects on non-users exposed to E-cigarette vapour. It has been suggested that the availability of these products could undermine current tobacco control initiatives. **There is ongoing scientific debate about whether E-cigarettes are an effective tool for smokers who want to quit. At the same time, there is general scientific consensus that the exclusive use of E-cigarettes is significantly less harmful than smoking. There is emerging evidence that E-cigarette use may substantially reduce the burden of disease caused by smoking.** (p.v)*

*In summary, there is emerging evidence that, if smokers switch completely to E-cigarettes, **these products pose less health risks to them than smoked tobacco but there is not yet enough data to confidently recommend these as a smoking cessation tool.** (p4) MoH Document.*

Though the Cancer Society agrees that E-cigarettes are less harmful than smoked tobacco, they are **not** harmless¹, and long –term health impacts are simply not known.

As a policy driver to replace smoked tobacco with e- cigarettes we are unaware of any research or evidence that shows:

- wholesale uptake of exclusive use of E-cigarettes by current smokers, or likelihood of this happening,

¹ (ASH Scotland, 2016)

- new smokers, who would have smoked tobacco products, choosing instead to use E-cigarettes exclusively, or
- Tobacco companies intending to totally switch from selling current tobacco products to E-cigarettes.

Our Position

The Cancer Society current position is that the evidence is still unclear on the overall risks and benefits associated with E-cigarettes, and that the status-quo is an appropriate policy option, until conclusive evidence emerges. We still hold this to be an acceptable position and urge that until stronger evidence and research in respect of the issues surrounding E-Cigarettes is undertaken no changes are made in New Zealand.

However, as noted above it would appear evident that regulation will be changed, therefore our submission is premised that though still maintain the status quo is appropriate we would (cautiously) consider changes to legislation and regulation *for the intention of increasing cessation, through the use of E-cigarettes, particularly among Māori, Pacific and other population groups who have high smoking rates.* We would not be supportive of changes that make them readily available and easily accessible, particularly to youth.

Purpose of submission:

The Cancer Society of New Zealand is committed to reducing the incidence and impact of cancer.

Smoking is the pre-eminent cause of lung cancer, and lung cancer is the leading single cause of cancer death. In 2012 the NZ Cancer Registry recorded 891 deaths for males and 737 for females from lung cancer.

Smoking also increases the risk of many other cancers including; larynx (voice box) oesophagus (gullet), mouth and pharynx (upper throat), bladder, pancreas, kidney, liver, stomach, bowel, cervix, ovary, nose and sinuses.

Smoking rates have declined from 23.5% in 1997 to 15% in 2014, but for Māori and Pasifika peoples, smoking rates remain high. Māori women are a particular cause for concern with a smoking rate of 41.8% in 2014^{2,3}.

We are supportive of evidence based policy that will further reduce smoking rates, reduce the incidence and impact of smoking related cancers, and reduce the health inequities experienced by Māori, Pacific and low socio-economic communities.

The Cancer Society is in agreement with the wider New Zealand Smokefree Sector consensus view that any changes in policy or regulation related to E-cigarettes should be guided by the following principles⁴ :

- New Zealand's tobacco control efforts should be maintained and intensified;
- The primary aim of the EC policy should be to support the achievement of the Smokefree 2025 goal for all population groups in New Zealand;
- It should minimise the risks initiation of nicotine use by non-smokers' (particularly children and young adults) either through long term EC use and/or via EC use to smoking;

² (MoH, 2008)

³ (MoH, 2015)

⁴ (Edwards R, 2016)

- Regulation of E-cigarettes should not be more stringent than regulatory measures in place for smoked tobacco products; and
- The Ministry of Health should continue to monitor emerging evidence on EC and the potential impacts of these products on smoking prevalence in New Zealand. Policy and practice should be updated in light of new evidence.

Our responses to the submission questions below outline the policy and regulation parameters we believe are required to allow support for cessation and protect consumers from the potential harm from E-cigarettes use.

Q2 Are there other (existing or potential) nicotine-delivery products that should be included in these controls at the same time? If so, what are they?

Yes No

Reasons/additional comments:

Any nicotine delivery devices should be included in these controls, as they are not risk free for the user.

The exception would be any products that have been through, or will go through, the Medsafe (or equivalent) process for use as a cessation support device.

These controls should also be future proofed to include future innovative products introduced onto the market.

Q3 Do you think it is important for legislation to prohibit the sale and supply of E-cigarettes to young people under 18 years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

Yes No

Reasons/additional comments:

There is a concern that E-cigarettes have the potential to promote smoking among young people⁵. Some E-cigarettes look like traditional cigarettes, and are marketed in a similar way overseas. They come in candy-like flavours, such as chocolate and fruit, which may appeal to and encourage young people to try these products. Where they are sold without legal age restrictions evidence indicates this may lead to young people to try other tobacco products, and they then may potentially become addicted to nicotine⁶.

Nicotine is an addictive substance and should be available only to over 18 year olds, in line with current Smokefree legislation. We recommend the requirement for sellers of both E-cigarette and tobacco products to be over 18 years old.

⁵ (US Food and Drug Administration, 2009)

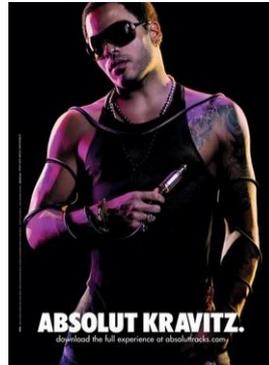
⁶ (US Food and Drug Administration, 2009)

Q4 Do you think it is important for legislation to control advertising of E-cigarettes in the same way as it controls advertising of smoked tobacco products?

Yes No

Reasons/additional comments:

E-cigarettes are already being advertised abroad in a manner similar to that used previously for cigarettes. They are portrayed as sophisticated, exciting, adult, and cool. (Examples below)



As can be seen it is also difficult to differentiate between E-cigarettes and traditional smoked tobacco from the imagery. This clearly has the potential to undermine the current regulations around tobacco advertising which are a cornerstone of the measures to reduce tobacco consumption and uptake, particularly among children and young people.

No advertising should be permitted outside of the point of sale at pharmacies and specialist vaping shops only. Any advertising allowed should not provide a gateway to also advertise tobacco products e.g. E-cigarettes packaging designed to mimic current cigarette packaging.

Point of sale advertising should be restricted to promoting cessation of smoking, to communicate the availability of E-cigarettes to smokers and advice about using them in quit attempts. We recommend the following:

- Targeted communications with smokers through health professionals, Quitline staff, cessation services, and at point of sale in pharmacies and specialist vape shops to provide information about the availability of E-cigarettes and their potential benefits and harms.
- Signage should be standardised nationally through the MoH/HPA, and regulated to avoid children and young people's exposure to marketing.

If advertising as a cessation product manufacturers should have research to support their claims of cessation support and be subject to scrutiny by the new modern therapeutic products regulatory regime and/or Medsafe.

Q5 Do you think it is important for the SFEA to prohibit vaping in designated smokefree areas in the same way as it prohibits smoking in such areas?

Yes No

Reasons/additional comments:

The, look use and smoke cloud created by E-cigarettes can be very similar to traditional tobacco products, and it can very difficult to discern the difference between the two.

Allowing E- Cigs to be used in Smokefree areas may therefore:

- undermine tobacco control laws and add to the impression that smoking is a normal behaviour - undermining the efforts to denormalise smoking.
- provide a trigger for those smokers who are trying to quit which may lead to relapse.

We would also add that that E-cigarettes regulations should be accompanied by the introduction of legislation to ban smoking in cars with children present, and national legislation to ban smoking in outdoor areas such as parks, playgrounds, sports fields, cafes and restaurants. This regulation, to ensure tobacco is not more freely available than E-cigarettes, should also be extended to cover tobacco smoking. These regulations should be part of the amended Smokefree Outdoor Area legislation being altered to accommodate E-cigarettes.

Q6 Do you agree that other controls in the SFEA for smoked tobacco products should apply to E-cigarettes? For example:

Control	Yes	No	Reasons/ additional comments
Requirement for graphic health warnings	<input checked="" type="checkbox"/>	<input type="checkbox"/>	We recommend pictorial Health Warnings that are clearly evident, and convey much more information than text alone (e.g. dangerous to ingest, keep away from children and pets). Warnings should include health information (that nicotine is addictive and that the long term health effects of EC use are not known), Quitline information, and a list of constituents. Inclusion of Quitline information is in line with the principle of maximising the use of E-cigarettes for cessation and to support the achievement of Smokefree 2025. Messages should be updated regularly as new evidence emerges as to known harms.
Prohibition on displaying products in sales outlets	<input checked="" type="checkbox"/>	<input type="checkbox"/>	E-cigarettes advertising “mimicking” traditional cigarette advertising (as noted above) is already evident overseas, and should not be allowed. Proven cessation messaging at point of sale in pharmacies and vape shops should be allowed in a standardised form to support cessation attempts.
Restriction on use of vending machines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Yes, prohibited as per Tobacco to restrict access to those under 18 and limit supply.

<p>Requirement to provide annual returns on sales data</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <p>Robust data and information is required to monitor the impact of these changes, and enable the monitoring of consumer, trends, and balance between independent and tobacco industry owned E-cigarettes on NZ market.</p> <p>Data would complement the tobacco sales/use and provide evidence to analyse impacts on cessation and reduced consumption of smoked tobacco.</p>
<p>Requirement to disclose product content and composition</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <p>Product content and composition should be monitored and regulated to prevent increased risk of harm from any potential changes to the initial ingredients and mix.</p> <p>We recommend that requirements to disclose product content and composition are aligned with best international practice, and that compliance with these standards is a condition for products to be approved for sale in New Zealand.</p> <p>We note no controls on nicotine content are applied to smoked tobacco products, though we believe there is a strong case for developing such controls, and that they be introduced at the same time as the E-cigarette regulations.</p>

<p>Regulations concerning ingredients (e.g., nicotine content and/or flavours) Examples of E-cigarette flavourings:</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <p>Ingredients should be regulated to reduce risk of harm to users.</p> <p>Ingredients can be added that change the way nicotine reacts and can increase addiction levels. These ingredients are already known from the tobacco industry use, and those should be banned from E-cigarettes, whilst also future proofing the regulation against innovative new ingredients⁷ (Europa DG Public Health and Consumer Protection, 2016).</p> <p>Flavours should not be required for E-cigarettes to be used as a cessation product, as there is no bad taste associated with E-cigarette use, as is found with smoked tobacco.</p> <p>Any approved flavours should have to go through a thorough testing to test for potential risks of harm.</p> <p>Any flavours allowed should not be of appeal to children or youth e.g. such as fruit, chocolate, sweets, lollies, menthol, (Example of E-cigarette flavourings to the left).</p> <p>We recommend that requirements for maximum concentration of nicotine are introduced aligned with best international practice, and that compliance with these standards is a condition for products to be approved for sale in New Zealand.</p> <p>We note no controls on nicotine content are applied to smoked tobacco products, though we believe there is a strong case for developing such controls and that they be introduced at the same time as E-cigarette regulations.</p>						
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Requirement for annual testing of product composition	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This would prevent any deviation of composition and prevent inclusion of ingredients that would increase the risk of harm, make use more attractive to youth and children, or increase the addictiveness of nicotine. We recommend aligning with credible international guidance for product composition testing.
Prohibition on free distribution and awards associated with sales	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This should be in line with current Smokefree regulation.
Prohibition on discounting	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This should be in line with current Smokefree regulation.
Prohibition on advertising and sponsorship	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This should be in line with current Smokefree regulation, and include social media outlets. E-cigarettes are already being advertised abroad in a manner similar to that used for smoked tobacco previously. They are portrayed as sophisticated, exciting, adult, and cool, and “mimicking” traditional cigarette advertising. Proven cessation messaging at point of sale in pharmacies and vape shops should be allowed.
Requirement for standardised packaging	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This should be in line with current Smokefree regulation. This would prevent attractiveness to youth and children and prevent uptake, and given the influence packaging has on gaining attention at the point-of-sale and its potential to stimulate impulse purchases. The example of plain packaging of pharmaceutical products could be applied to E-cigarettes.
Other	<input type="checkbox"/>	<input type="checkbox"/>	

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, as it does on tobacco products?

Yes No

Reasons/additional comments:

As first stated if E-Cigarettes are regulated to allow cessation support it would be important for E-cigarettes to be affordable, and not attract additional excise tax.

However, introduction of E-cigarettes to the marketplace needs to be monitored, and should the evidence indicate a substantial uptake of E-cigarette use by children or young people then additional excise needs to be an option.

In general prices should be cheaper than current cigarette and tobacco prices to encourage uptake from current smokers, however pricing should also be such that it is out of range for children and young people to prevent curiosity uptake.

Above inflation excise increases should continue on tobacco products.

Q8 Do you think quality control of and safety standards for E-cigarettes are needed?

Yes No

Additional comments: The Cancer Society notes that the current market for E-Cigarettes is predominantly made up of small manufacturers, with a growing interest by the International Tobacco Companies.

We acknowledge that any regulations need to balance the ability of smaller manufacturers to meet the requirements, as we do not inadvertently wish to make Tobacco companies the only possible providers.

However we are equally clear that it is a fair expectation that manufacturers can assure customers of what is in their product, the quality of the product, the known harm associated with use as intended by them, and there is safety of packaging.

We provide more detailed responses below.

Area of concern	Yes	No	Reasons/additional comments
Childproof containers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>There are child safety issues in terms of children opening and swallowing the contents of nicotine cartridges, which are not generally sold in child resistant containers, with the possible risk of choking or nicotine poisoning^{7,8}.</p> <p>Research shows nicotine poisoning of children from E-cigarettes has increased significantly, with severe outcomes for some children⁹.</p> <p>Containers should be childproof, should not look appealing, or contain flavourings/smells that appeal to children. We recommend that minimum standards of child safety, aligned with best international practice, and that compliance with these standards is a condition for products to be approved for sale in New Zealand.</p>

⁸ (Health Canada, 2009)

⁹ (Kamboj A, 2016)

Safe disposal of E-cigarette devices and liquids	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The disposal of devices and liquids should not impact negatively on the environment, whether through increased waste/litter, or residue entering the waterway.
Ability of device to prevent accidents	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The products need to be safe for storage and use. US research show at least 25 Fires and explosions from E-cigarettes, so there is a need to ensure physical safety of users ¹⁰
Good manufacturing practice	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This will ensure that products are consistently produced and controlled according to quality standards to minimise the risks involved with E-cigarette use. We recommend analysis of best international practice, and requiring compliance with these standards as a condition for products to be approved for sale in New Zealand.
Purity and grade of nicotine	<input checked="" type="checkbox"/>	<input type="checkbox"/>	This will ensure purity and grade of nicotine used is at the agreed level according to the new standards put in place by the regulatory regime. This will prevent low grade or mixed products being used to cut costs, which may also increase risk of harm. We recommend that requirements align with best international practice, and that compliance with these standards is a condition for products to be approved for sale in New Zealand.
Registration of products	<input checked="" type="checkbox"/>	<input type="checkbox"/>	All products should be registered and have to undergo thorough testing according to the standards set by the new regulatory regime. We recommend that registration of products and demonstration of compliance with international standards is a condition for products to be approved for sale in New Zealand.

¹⁰ (U.S. Department of Homeland Security, 2014)

<p>A testing regime to confirm product safety and contents purity</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>This reduces risk of increased harm to consumers.</p> <p>Currently, E-cigarettes are not manufactured to the same rigorous standards as pharmaceutical products, and research has found a number of quality control concerns and health issues¹¹.</p> <p>The FDA found different amounts of nicotine in or emitted from E-cigarettes than were contained on the labels, and while some E-cigarettes were marketed as containing no nicotine, they did in fact contain nicotine¹². Other researchers ^{1,7} have reported similar variable nicotine delivery.</p> <p>Because E-cigarettes are not regulated, each brand and batches within a brand may vary, which could impact on effectiveness and safety research.</p>
<p>Maximum allowable volume of e-liquid in retail sales</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>We recommend a maximum purchase/sale regulation is introduced in line with what is reasonable for personal use. The rationale for this is to prevent bulk purchase for the purposes of supplying/selling to others, which would circumvent the restrictions on sales and supply (particularly to minors) and the requirement that sales staff can provide expert advice in use of ECs and brief smoking cessation advice and referral.</p>
<p>Maximum concentration of nicotine e-liquid</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>We recommend up to the equivalent concentration of 18mg nicotine per gram of tobacco, as present in the average cigarettes found in New Zealand¹³. .</p> <p>However we would also consider that maximum concentration of nicotine are aligned with best international practice, and that compliance with these standards is a condition for products to be approved for sale in New Zealand.</p> <p>We note no controls on nicotine content are applied to smoked tobacco products. We recommend that control and monitoring of nicotine concentrations in E-cigarettes and tobacco are aligned and legislation for both is introduced simultaneously.</p>

¹¹ (Trtchounian, 2011)

¹² (Westenberger, 2009)

¹³ (Laugesen, 2012)

Mixing of e-liquids at (or before) point of sale	<input checked="" type="checkbox"/>	<input type="checkbox"/>	We recommend that regulations state mixing of e-liquids should take place in pharmacies and specialist vape shops at point of sale and be performed by trained staff expert in the use of ECs and e-liquids, to ensure safety of the products.
Other	<input type="checkbox"/>	<input type="checkbox"/>	

Q9 Are there any other comments you would like to make?

Yes.

It is essential that the proposed new modern therapeutic products regulatory regime is fully in place prior to implementation of any E-cigarette regulations, or release onto the local market.

For the purposes of writing legislation any person that makes, modifies, mixes, manufactures, fabricates, assembles, processes, labels, repacks, relabel, or imports ENDS are all classed as manufacturers and must register with the new regulatory regime and comply with all requirements for a manufacturer. This would align New Zealand's regulations with the US Drug Administration with regards to ENDS²

Additional information on sales and use

Q10 Can you assist us by providing information on the sale of E-cigarettes in New Zealand (for example, size of sales or range of products for sale on the local market)?

No

Q11 Would the Ministry of Health's proposed amendments have any impact on your business? If so, please quantify/explain that impact.

Not applicable

Q12 If you are using nicotine E-cigarettes: how long have you been using them, how often do you use them, how much do you spend on them per week and where do you buy them?

How long have you been using them?	How often do you use them?	How much do you spend on them per week?	Where do you buy them?
N/A			

Submitter information

The Cancer Society of New Zealand is a Federation of six Divisions and a National Office. We are committed to helping reduce the incidence and impact of cancer on the community. Cancer affects many of us and is a major cause of disease, disability and death in New Zealand, with 21,050 new registrations and 8,891 deaths in 2011 (Ministry of Health 2015). To lessen this impact, we need an organised approach to reduce the number of people who die from cancer and improve the quality of life of those who are diagnosed.

As part of our approach, the Cancer Society has a set of objectives, including:

- a) Providing supportive care and information to people affected by cancer, their families/whanau and carers.*
- b) Encouraging, organising, supporting and funding research within New Zealand into the prevention, treatment and cure of cancer.*
- c) Delivering health promotion programmes focusing on cancer prevention.*
- d) Leading advocacy across the cancer continuum.*
- e) Promoting education about cancer for health professionals and publicising progress made in research and treatment.*
- f) Working collaboratively with other organisations who share similar goals to the Cancer Society.*

Cancer Society staff also participate in Regional Cancer Networks, which were set up by the Ministry of Health in 2008. These networks have District Health Boards (DHB's), Primary Care, Non-Government Organisations (NGO's) and Consumer representatives.

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