



Submission to Senate Select Committee on Tobacco Harm Reduction

Submitted on behalf of European Tobacco Harm Reduction Advocates on 3rd November 2020

Executive Summary

1. The EU Tobacco Products Directive's failure to regulate according to risk has led to major shortcomings. Brexit offers the UK an opportunity to put a coherent risk-based policy in place.
2. Vaping is displacing smoking in countries where vaping remains accessible and affordable.
3. Randomised control trials and population level data from national surveys across Europe show that vaping is effective for smoking cessation.
4. Vaping does not lead to youth smoking: population level data across Europe shows a continued decline in smoking rates across all age groups.
5. The European experience shows that accessibility of vaping products is crucial to vaping's success at leading smokers away from smoking. The prescription model currently under consideration in Australia would severely restrict access and its adoption would keep Australia smoking.

European Tobacco Harm Reduction Advocates

European Tobacco Harm Reduction Advocates (ETHRA) is a group of 22 consumer associations in 16 European countries, representing approximately 27 million¹ consumers across Europe and supported by scientific experts in the field of tobacco control or nicotine research. We are mostly ex-smokers who have used safer nicotine products, such as vapes and snus, to quit smoking and to remain smoke free.

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ETHRA is not funded by the tobacco or vaping industry, in fact we are not funded at all as our grouping is a voice for our partners who arrange their own revenue and who give their time to ETHRA for free. Our mission is to give consumers of safer nicotine products a voice and to ensure that the full harm reduction potential of safer nicotine products is not hindered by inappropriate regulation. ETHRA is listed in the EU Transparency Register at: [354946837243-73](https://ec.europa.eu/transparency/regexp1/index.cfm?do=groupDetail.groupDetail&id=354946837243-73).

Our knowledge of the tobacco harm reduction landscape in Europe together with our own personal experiences as ex-smokers who have used safer nicotine products to quit, qualify us to comment here.

Select Committee on Tobacco Harm Reduction terms of reference

We respond to four of the areas specified by the Committee:

1. The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks
2. The impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption;
3. The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment;
4. The established evidence on the uptake of e-cigarettes amongst non- smokers and the potential gateway effect onto traditional tobacco products;

1. The treatment of nicotine vaping products (electronic cigarettes and smokeless tobacco) in developed countries similar to Australia (such as the United Kingdom, New Zealand, the European Union and United States), including but not limited to legislative and regulatory frameworks

The Tobacco Products Directive (TPD)ⁱ regulates the manufacture, sale and presentation of most safer nicotine products, as well as combustible tobacco products, across the EU.

The TPD is the most comprehensive regulatory framework worldwide and is also the only regional framework. The TPD regulates vaping and heated tobacco products but bans the sale of snus, except for in Sweden.

For us consumers, living with the TPD is a mixed bag. A substantial benefit is that the inclusion of vaping products in the directive prevents EU member states from banning the products. However, the TPD has many limitations, at the root of which is its failure to distinguish between combustion and non-combustion.

Combustible cigarettes are harmful to health because smoking involves the inhalation of burned matter. Safer nicotine products do not involve combustion and so are far less risky to health. Products should therefore be regulated according to whether they are combustible or not, as combustion is where most of the harm lies. The TPD places both the dangerous and the far safer products in the same directive and applies similar regulations to both. The TPD therefore draws a distinction between nicotine and non-nicotine containing products, a distinction which is meaningless in terms of health.

Consequently, some of the TPD restrictions for safer products are excessive in relation to their risk, and deter smokers from adopting the less harmful products. Nicotine concentration in e-liquids is capped at 20mg/ml, a level too low for many smokers. Refill container and tank volumes are too small, which is inconvenient for consumers and leads to high levels of plastic waste. The TPD mandated health warnings massively overstate the risks of using the products and put people off from switching. The excessive advertising restrictions prevent smokers from learning about these novel products or the benefits of switching.

Another failure of the TPD is that it allows member states the freedom to apply more restrictive regulations. An example of this “gold plating” is online sale bans, adopted by some member states. During the COVID-19 lockdowns in Belgium and Finland the online sales bans meant that consumers could not purchase vaping products, yet cigarettes remained widely available. We are very concerned that ex-smokers in Belgium and Finland will have been forced to return to smoking.

The TPD’s biggest failing is its ban on the sale of the oral tobacco product snus. Snus has played a key role in reducing smoking rates in Sweden to <5%ⁱⁱ, with huge benefits to public health. Using snus is far less risky to health than smoking, yet the TPD denies smokers access to it.

The UK has been the most successful at making the most of the public health opportunities offered by vaping products while operating within the constraints of the TPD. The UK's National Health Service promotes vaping as a means to try stopping smoking and advertisements for the government's annual Stoptober campaign regularly feature middle-aged people vaping. The UK has a ban on sales to under 18's – remarkably, not all of the EU member states do. Data on youth smoking and vaping is regularly collected and show that vaping uptake among non-smoking youth is negligible.

Brexit offers an opportunity for the UK to diverge from the TPD restrictions. ETHRA partner New Nicotine Alliance UK recently wroteⁱⁱⁱ to the UK government to ask for revisions to the UK's tobacco and nicotine policy, *“to promote both public health and personal and economic wellbeing”*. Below are NNA UK's ten proposed reforms. We strongly recommend also reading NNA's *“Briefing: post-Brexit reform of EU-derived tobacco and vaping regulation”* which sets out the case for the reforms and is part of the same document.

New Nicotine Alliance UK's 10 reforms to UK tobacco and nicotine policy

1. Lift the ban on oral tobacco (snus) and properly regulate all smokeless tobacco
2. Raise the limit on nicotine concentration in vaping liquids to allow vaping products to compete more effectively with cigarettes
3. Replace bans on advertising of vaping products on TV, radio, internet and in publications with controls on themes and placement
4. Replace blanket bans on advertising of low-risk tobacco products with controls on themes and placement
5. Replace excessive and inappropriate warnings on vaping products with risk communications that encourage smokers to try switching
6. Replace excessive and inappropriate warnings on non-combustible tobacco products
7. Allow and enable candid communication of relative risk to consumers
8. Adopt a fresh approach to pack inserts for both vaping products and cigarettes to encourage switching to lower risk products
9. Remove wasteful restrictions on vaping product tank and e-liquid container size that have no discernible purpose
10. Recognise and regulate novel oral nicotine products

(NNA UK letter re tobacco policy, 29 October 2020, page two)

2. The impact nicotine vaping products have had on smoking rates in these countries, and the aggregate population health impacts of these changes in nicotine consumption;

Vaping is displacing smoking in individual countries where vaping remains accessible and affordable, and we discuss France, Ireland and the UK below.

The most directly applicable study for the EU region draws on the EU's Eurobarometer survey.^{iv v}

An estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the use of ecigarettes respectively.

This relates to 2014 survey data, so we would expect far more by now.

France: In the French Baromètre de Santé public France^{vi} vapers aged 18 to 75 have almost all used tobacco, as current or former smokers. Between 2014 and 2017, the proportion of daily smokers decreased among vapers (from 64.5% to 39.7%), while that of ex-smokers increased (from 23.5% to 49.5%). The number of daily ex-smokers who quit smoking for more than six months and who think that vaping helped them quit is estimated at around 700,000, since the availability of e-cigarettes on the French market.

Ireland: The Healthy Ireland Survey^{vii} commissioned by HSE (public health) shows that the smoking rate in 2015 and 2016 was 23%. This is about the time that vaping products were becoming popular. From 2017 until last year smoking rates plummeted to 17%. The survey shows that over those years 39% of successful quit attempts were made by people using e-cigarettes. Vaping prevalence in Ireland was 3% in 2015 and rose to 5% last year.

UK: Public Health England's 2020 review^{viii} found that smoking among adults in England has continued to decline over the past ten years and in 2019 was around 15%. The same review found that:

"Vaping remains most common among smokers and former smokers, with less than 1% of people who have never smoked currently vaping",

and that:

"data from stop smoking services in England suggests that when a vaping product is used in a quit attempt, either alone or with licensed medication, success rates are comparable to, if not higher than, licensed medication alone."

(see 4.1, Vaping among adults, main findings)

ASH's 2019 *Use of e-cigarettes (vaporisers) among adults in Great Britain*^x on the association between quitting smoking and vaping:

“... the Smoking Toolkit Study (an ongoing series of monthly surveys of the adult population of England) has shown a clear association between changes in population rates of quitting smoking and prevalence of e-cigarette use after adjusting statistically for a range of potential confounding factors. If the association is causal, e-cigarettes were responsible for an estimated 69,930 additional ex-smokers in England in 2017. Furthermore, recent evidence from a randomised controlled trial showed that vaping was nearly twice as effective as NRT in helping smokers quit in a Stop Smoking Service setting in England.” (see page 4)

Vaping and snus are far less harmful to health than smoking. Due to the long-term nature of effects of smoking on health, positive health impacts from people displacing their smoking with vaping will take a long time to establish. However, snus provides us with a natural experiment. Snus has been in use for around two hundred years and reliable data has been collected for the past twenty years. Swedish snus is far less risky to health than smoking and there is clear evidence that snus not only lowers the smoking prevalence, but that this translates to a lower burden of disease. The Global Burden of Disease Study^x summarises the health risks of snus as follows:

Based on available evidence, for chewing tobacco Risk Ratios were significantly higher than one for oral cancer and oesophageal cancer, while for snus or snuff we did not find sufficient evidence of a Risk Ratio greater than one for any health outcome.”

This has been recognized in the USA where the FDA granted Swedish Snus the first ever modified risk order in 2019^{xi}. The FDA states that:

“the modified risk products, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole.”

Given that vaping has consistently been found to carry only 5% of the risks of smoking^{xii}, we would expect a widespread uptake of vaping products to translate to a low disease burden.

3. The established evidence on the effectiveness of e-cigarettes as a smoking cessation treatment;

Randomised control trials and population level data from national surveys across Europe show that vaping is effective for smoking cessation. The most recent Cochrane review^{xiii} concludes that e-cigarettes are 67% more effective than Nicotine Replacement Therapies (Hartmann-Boyce et al., 2020). Two earlier randomised control trials, Hajek, *et al* (2019)^{xiv} and Walker *et al* (2020)^{xv} also show that e-cigarettes are significantly more effective than Nicotine Replacement Therapy (NRT).

In the case of Hajek et al, e-cigarettes were 83% more effective than NRT's, and Walker et al found e-cigarettes combined with NRT's to be 2.5 times more effective than patches alone.

Data from national surveys provide strong evidence that e-cigarettes have contributed to a reduction in smoking prevalence:

The Health Ireland survey for 2019^{xvi} shows that smoking prevalence fell 6% in 3 years with 38% of successful quitters using e-cigarettes, compared to only 15% using pharmacological products.

Santé Publique France found that more than 700,000 people have used e-cigarettes to stop smoking in the long term in 2017 and that vaping is the most common method used to quit smoking in France (Pasquereau et al., 2017)^{xvii}.

4. The established evidence on the uptake of e-cigarettes amongst non- smokers and the potential gateway effect onto traditional tobacco products;

The precept that vaping leads to smoking is very controversial, and Public Health England has cautioned against using gateway terminology: *"We strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field."* (McNeill et al., 2015, page 38)^{xviii}.

If it did hold water – if vaping does lead to smoking - we would be seeing rises in youth smoking rates by now. However, population level data from across Europe shows a continued decline in smoking rates across all age groups.

Belgium: The 2018 Health Survey on the use of electronic cigarettes^{xix} concludes that the majority of youth (15 to 24 years old) experimentation does not seem to lead to regular use

and that daily use is relatively low (0.6%). In the overall population, 90% of Belgian vapers used to smoke cigarettes.

France: The OFDT monitoring of high school students shows that daily smoking dropped from 23.2% in 2015 to 17.5% in 2018, while almost daily vaping reached 2.8% in 2018. Using this data, a study examined specifically if vaping among adolescents is associated with subsequent smoking initiation^{xx}: *“Among ever-smokers, adolescents who declared having ever used e-cigarettes were less likely than those who did not to transition to daily smoking at 17. We found similar results for those who experimented with e-cigarettes before initiating smoking”*, concluded the researchers.

Germany: The German Cancer Research Centre report (DKFZ, 2020)^{xxi} found scant evidence for a gateway effect at population level. *“Even if numerous studies suggest a connection between e-cigarette consumption and smoking, this has apparently only had little and different effects at the population level”*.

Ireland: Youth smoking in Ireland has fallen to 5.9%. There is no official data for youth vaping rates in Ireland, but the Healthy Ireland survey participants are from 15 years up. Healthy Ireland 2019 data^{xxii} finds that never smokers that vape is 1% and has been consistently <1% since the survey started in 2015.

UK: Data from the 2019 ASH YouGov Smokefree youth GB survey^{xxiii} suggest that while some young people, particularly those who have tried smoking, experiment with e-cigarettes, regular use remains low. Regular use of e-cigarettes remains largely confined to current or ex-smokers. Not a single never smoker reported vaping daily and only 0.1% vaped more than once a week.

Do adolescents find vaping attractive? A study of young vapers in Norway^{xxiv} finds that they do not, reporting that:

“... vaping had lost status and was described as ‘childish’ and unpopular.. comparing e-cigarettes with the fidget-spinner and reserving vaping for kids and addicted adult smokers. E-cigarettes were devalued from novelty and transgression to childish and uninteresting within the same sample over a four-year period. In conclusion, e-cigarettes in the sample represented fashionable experimentation rather than steady user patterns”

To those of us who spend time with adolescents, this finding rings very true - and we might even regret that vaping is not more attractive to adolescents, when we consider the other far

riskier behaviours which adolescents are otherwise drawn to (alcohol, unprotected sex, drug taking, etc).

To conclude

Australia has an exciting opportunity to develop world leading regulations for safer alternatives to smoking, regulations based on science and which maximise the public health gains from allowing smokers to access these lifesaving alternatives. We are concerned to learn that Australia is instead considering a prescription model. As we have shown here, vaping is effective where it is accessible, affordable and where there is a wide range of choice. The prescription model works against all those elements and will keep Australians smoking.

Sources

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- ⁱ Tobacco Products Directive (2014/40/EU), https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf
- ⁱⁱ Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *Int J Environ Res Public Health*. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5129320/>
- ⁱⁱⁱ Letter to the government from New Nicotine Alliance on post-Brexit policy options for tobacco and nicotine https://nnalliance.org/images/documents/Letter_re_tobacco_policy_-_201029.pdf
- ^{iv} Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*. 2016 Jun 24; <http://onlinelibrary.wiley.com/doi/10.1111/add.13506/full>
- ^v Farsalinos KE, Poulas K, Voudris V, Le Houezec J. E-cigarette use in the European Union: millions of smokers claim e-cigarettes helped them quit. *Addiction*. 2017 Mar;112(3):545–6. <http://onlinelibrary.wiley.com/doi/10.1111/add.13722/full>
- ^{vi} Pasquereau, Anne & Quatremère, Guillemette & Guignard, Romain & Andler, Raphaël & Verrier, Florian & Pourchez, Jeremie & Richard, Jean-Baptiste & Nguyen-Thanh, Viêt. (2019). USAGE DE LA CIGARETTE ÉLECTRONIQUE, TABAGISME ET OPINIONS DES 18-75 ANS Baromètre de Santé publique France 2017
- ^{vii} Department of Health (2019) *Healthy Ireland. Summary Report 2019*. Available at: <https://assets.gov.ie/41141/e5d6fea3a59a4720b081893e11fe299e.pdf>.
- ^{viii} Public Health England. Vaping in England: an evidence update including mental health and pregnancy, March 2020 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869401/Vaping_in_England_evidence_update_March_2020.pdf

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- ^{ix} Action on Smoking and Health / YouGov. Use of e-cigarette (vaporisers) among adults in Great Britain in 2019. <https://ash.org.uk/wp-content/uploads/2019/09/Use-of-e-cigarettes-among-adults-2019.pdf>
- ^x Gakidou E, Afshin A, Abajobir AA, Abate KH, Abbafati C, Abbas KM, et al. A systematic analysis for the Global Burden of Disease Study 2016. *Lancet*. 2017 Sep 16;390(10100):1345–422. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32366-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32366-8/fulltext)
- ^{xi} Food and Drug Administration (United States). FDA grants first-ever modified risk orders to eight smokeless tobacco products, 22 October 2019 <https://www.fda.gov/news-events/press-announcements/fda-grants-first-ever-modified-risk-orders-eight-smokeless-tobacco-products>
- ^{xii} Public Health England. Vaping in England: an evidence update including mental health and pregnancy, March 2020 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/869401/Vaping_in_England_evidence_update_March_2020.pdf
- ^{xiii} Hartmann-Boyce, J. *et al.* (2020) 'Electronic cigarettes for smoking cessation', *Cochrane Database of Systematic Reviews*, (10). doi: 10.1002/14651858.CD010216.pub4.
- ^{xiv} Hajek, P. *et al.* (2019) 'A randomized trial of E-cigarettes versus nicotine-replacement therapy', *New England Journal of Medicine*, 380(7), pp. 629–637. doi: 10.1056/NEJMoa1808779.
- ^{xv} Walker N, Parag V, Verbiest M, Laking G, Laugesen M, Bullen C. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomised trial. *Lancet Respir Med*. 2020 Jan;8(1):54-64. doi: 10.1016/S2213-42 2600(19)30269-3
- ^{xvi} Department of Health (2019) *Healthy Ireland. Summary Report 2019*. Available at: <https://assets.gov.ie/41141/e5d6fea3a59a4720b081893e11fe299e.pdf>.
- ^{xvii} Pasquereau A, Quatremère G, Guignard R, Andler R, Verrier F, Pourchez J, Richard JB, Nguyen-Thanh V and the Sant Barometer group. Public health France 2017. Public health barometer Francid 2017. Use of electric cigarettes, smoking and views of 18-75-year olds. Saint - Maurice: Public health France, 2019. 17 p
- ^{xviii} McNeill, A. *et al.* (2015) 'E-cigarettes : an evidence update', *Public Health England*, p. 111.
- ^{xix} Sciencsano (Belgium), 2018 Health Interview Survey on the use of electronic cigarettes <https://his.wiv-isp.be/SitePages/Reports.aspx>, PDF https://his.wivisp.be/fr/Documents%20partages/EC_FR_2018.pdf
- ^{xx} Chyderiotis, S. *et al.* (2020) 'Does e-cigarette experimentation increase the transition to daily smoking among young ever-smokers in France?', *Drug and Alcohol Dependence*, 208(November 2019), p. 107853. doi: 10.1016/j.drugalcdep.2020.107853.
- ^{xxi} Deutsches Krebsforschungszentrum. (2020) 'E-Zigaretten und Tabakerhitzer – ein Überblick'.
- ^{xxii} Department of Health (2019) *Healthy Ireland. Summary Report 2019*. Available at: <https://assets.gov.ie/41141/e5d6fea3a59a4720b081893e11fe299e.pdf>.
- ^{xxiii} Action on Smoking and Health (ASH) (2019) 'Use of e-cigarettes among young people in Great Britain', *Action on Smoking and Health website*, (September), pp. 1–14. Available at: <http://ash.org.uk/category/information-and-resources/%0Ahttps://ash.org.uk/wp-content/uploads/2019/06/ASH-Factsheet-Youth-E-cigarette-Use-2019.pdf>.
- ^{xxiv} Tokle R (2020). 'Vaping and fidget-spinners': A qualitative, longitudinal study of e-cigarettes in adolescence. *International Journal of Drug Policy* Volume 82, August 2020, 102791. Available at: <https://doi.org/10.1016/j.drugpo.2020.102791>