



21<sup>st</sup> of August 2020

Dear Magnus Heunicke, Minister for Health and the Elderly,

European Tobacco Harm Reduction Advocates (ETHRA) is a group of 21 consumer associations in 16 European countries, representing approximately 27 million consumers<sup>1</sup> 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. 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.

**Dansk e-Damper Forening (DADAFO)**, the Danish consumer organisation, is a partner for ETHRA and DADAFO's chairman Kim Dabelstein Petersen and treasurer Peter Stigaard have signed this letter on behalf of all of us. ETHRA is listed in the EU Transparency Register at: 354946837243-73 and DADAFO is listed at: 220201831871-76.

We are writing today to comment on the *Bill amending the Act on the ban on tobacco advertising etc*<sup>2</sup> with regards to its provisions for safer nicotine products, to outline why these measures are detrimental to public health. We are also submitting this as a contribution to the TRIS notification for the Bill: 2020/0228/DK.

We are concerned that the Bill will deny Denmark's 786.000 adult smokers a route away from the deadly combustible cigarette and will also make it very difficult for Denmark's 250.000 vapers to remain smoke free.

Several provisions in the Bill seek to regulate safer nicotine products as strictly as combustible tobacco products, despite the huge difference in risks to health. The ban on flavourings, the display ban, the stricter ban on advertising and sponsorship, the introduction of standardised packaging and various measures which will make vaping more expensive will prevent adults from switching to safer alternatives and so will prolong smoking.

Main points in this letter:

1. [The disproportionate focus on youth will lead to unintended consequences for adults.](#)
2. [Regular youth vaping is rare and youth experimentation with safer nicotine products does not result in increased youth smoking](#)
3. [Flavours are crucial for winning smokers over to safer products](#)
4. [Combustion is the problem, not nicotine](#)
5. [Smokers have a right to accurate information about safer products.](#)
6. [Making safer products more expensive will deter smokers from switching](#)

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<sup>1</sup> Estimate of 27 million consumers provided by ECigIntelligence/TobaccoIntelligence. The actual figure is likely to be far higher because the data for smokeless tobacco is taken from research (Leon et al 2016) using data gathered in 2010 in only 17 countries.

<sup>2</sup> Bill amending the Act on the ban on tobacco advertising etc., Act on tobacco products etc., Act on electronic cigarettes etc. and various other acts (Implementation of the national action plan against smoking by children and young people) TRIS notification detail [\[access\]](#)

## 1. The disproportionate focus on youth will lead to unintended consequences for adults

It has long been known that “people smoke for the nicotine and die from the tar”<sup>3</sup>. The harms from smoking are caused by combustion - the method of delivery used to get nicotine - and not by nicotine itself. Nicotine in regulated safer nicotine products is not harmful: the risk profile for vaping nicotine in e-liquids is similar to that of drinking coffee<sup>4</sup>. Safer nicotine products do not involve combustion and so avoid most of the harms associated with smoking. Popular safer nicotine products include vapes, snus, nicotine pouches (included as “tobacco substitutes” in the Bill) and heated tobacco products. “Tobacco harm reduction” refers to use of these products by people like us, smokers and former smokers who wish to reduce their exposure to the harms of smoking.

Quitting smoking can be very difficult and relapse to smoking is common: for many smokers it can take up to 30 quit attempts before being successful<sup>5</sup>. This is why it is imperative that all smoking cessation options are available to smokers. Safer nicotine products have the potential to reach more smokers if they are widely available as a consumer product.

Safer nicotine products are effective. Vaping has been shown to be 83% more effective than nicotine replacement therapy (NRT) for smoking cessation<sup>6</sup> and has successfully displaced smoking in countries where it is widely available<sup>7</sup>. Snus is a pasteurised smokeless tobacco product that has been used in Scandinavia for centuries. Snus has replaced smoking at such an extraordinary rate in Sweden, Norway and Iceland that these countries are now close to the point of being smoke free (having a smoking prevalence of 5% or lower). Swedish snus is far less risky to health than smoking. This has been recognised by the US FDA which granted Modified Risk Orders to snus products in October 2019<sup>8</sup>. The Global Burden of Disease Study summarises the health risks of snus as follows:<sup>9</sup>

*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.”*

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<sup>3</sup> Tobacco harm reduction, Wikipedia [\[access\]](#)

<sup>4</sup> Britton J. E-cigarettes and the precautionary principle. BMJ Opinion. 20 Sept 2019 [\[access\]](#)

<sup>5</sup> Chaiton M, Diemert L, Cohen JE, et al. Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers. BMJ Open. 2016;6: e011045n[\[access\]](#)

<sup>6</sup> Hajek P, Phillips-Waller A, Przulj D, et al. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. N Engl J Med. 2019;380(7):629-637. doi:10.1056/NEJMoa1808779 [\[access\]](#)

<sup>7</sup> Interview on Tobacco Products Directive: notes by ETHRA, pps 8-9 Impact of e-cigarettes on smoking cessation [\[access\]](#)

<sup>8</sup> FDA Authorizes Modified Risk Tobacco Products, FDA website accessed 18 August 2020 [ [access](#) ]

<sup>9</sup> 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. [\[access\]](#)

Like snus, vaping products have also been shown to be far safer than smoking. The Royal College of Physicians stated in its 2016 report *Nicotine Without Smoke*<sup>10</sup> that

*“the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure”.*  
(Section 5.5 page 87).

Regulations for safer products should therefore be based on risk in relation to combustible cigarettes, not according to whether products contain nicotine or tobacco. Inappropriate regulations that make safer nicotine products (SNPs) less desirable to adults, more inconvenient or expensive to use, and increase misperceptions of harm can themselves cause harm by deterring smokers from switching – and so prolong smoking.

The Royal College of Physicians in the UK warned that making vaping products harder to access results in increased smoking:

*“However, if [a risk-averse, precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking.”*  
<sup>11</sup>(Section 12.10 page 187).

We regret that the Bill will do all these things and so deny Denmark’s 780,000 smokers and 250,000 vapers the right to improve their own health.

## ***2. Regular youth vaping is rare and youth experimentation with safer nicotine products does not result in increased youth smoking***

The key intention for the Bill is to “reduce the number of smokers, particularly for fewer young people to start smoking or become addicted to other nicotine products”<sup>12</sup>. However, there is no evidence that youth vaping gives rise to youth smoking.

In the United States, more detailed analysis of the headline numbers driving the concern about youth vaping<sup>13</sup> shows that most adolescent vaping is infrequent and by far the majority of frequent adolescent e-cigarette users had previously smoked. For them, the uptake of vaping may be beneficial if it forms a short- or long-term diversion from smoking. The data suggest that despite the sharp rise in youth vaping, it is not adding substantially to overall nicotine dependence:

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<sup>10</sup> Royal College of Physicians (London). *Nicotine without smoke: tobacco harm reduction*. April 2016 [[access](#)]

<sup>11</sup> Royal College of Physicians (London). *Nicotine without smoke: tobacco harm reduction*. April 2016. Section 12.10 page 187 [[access](#)]

<sup>12</sup> See Impact Assessment [[access](#)]

<sup>13</sup> West R, Brown J, Jarvis M. Epidemic of youth nicotine addiction? What does the National Youth Tobacco Survey reveal about high school e-cigarette use in the USA? (Preprint). *Qeios*. 2019 Oct 7; <https://www.qeios.com/read/745076.3>

*"Data from the NYTS [US National Youth Tobacco Survey] do not support claims of a new epidemic of nicotine addiction stemming from use of e-cigarettes, nor concerns that declines in youth tobacco addiction stand to be reversed after years of progress. Among current e-cigarette users who had never tried tobacco products, responses consistently pointed to minimal dependence."*

While any teenage use of nicotine is undesirable, infrequent vaping is among the least concerning of youth risk behaviours when compared, for example, to smoking, illicit drug use, teenage pregnancy, binge drinking, or drink-driving or to the other problems that afflict young people, such as bullying, or mental health problems.

Here are some findings from countries where - as in Denmark - the EU Tobacco Products Directive applies:

Belgium: The 2018 Health Survey<sup>14</sup> on the use of electronic cigarettes concludes that the majority of experimenting with electronic cigarettes by youth (15 to 24 years old) does not seem to lead to regular use and that daily use is relatively low (0,6%). In the overall population 90% of vapers used to smoke cigarettes.

France: The OFDT monitoring of high school students<sup>15</sup> 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: *"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.

UK: Data from the 2019 ASH YouGov Smokefree youth GB survey<sup>16</sup> 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. We would like to note here that the UK has restricted sales of vaping products to over-18's since 2018, which could be a factor in the low youth vaping prevalence.

Ireland: Youth smoking in Ireland has fallen to 5.9%.<sup>17</sup> There is no official data for youth vaping rates in Ireland but the Healthy Ireland survey participants are from 15 years up.

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<sup>14</sup> Sciencsano (Belgium). 2018 Health Interview Survey on the use of electronic cigarettes [\[access\]](#)[\[PDF\]](#)

<sup>15</sup> S. Chyderiotis, T. Benmarhnia, F. Beck, S. Spilka, S. Legleye. Does e-cigarette experimentation increase the transition to daily smoking among young ever-smokers in France? Drug and Alcohol Dependence. 208 (2020). Article 107853, 10.1016/j.drugalcdep.2020.107853 [\[access\]](#)

<sup>16</sup> Action on Smoking and Health (UK). Use of e-cigarettes among young people in Great Britain. 2019 [\[access\]](#)

<sup>17</sup> Health Service Executive (Ireland). Youth Smoking in Ireland: A special analysis of the Health Behaviour in School-aged Children (HBSC) study. 2018 [\[access\]](#)

Healthy Ireland 2019 data finds that never smokers that vape is 1% and has been consistently <1% since the survey started in 2015.

The available data show that in Denmark too young people are not very interested in vaping and that youth smoking rates are low:

Denmark: The Survey of School Children 2014<sup>18</sup> found that 19.75% of 11 to 15-year olds had experimented with vaping (ever use). In 2018 that figure had fallen to 11%<sup>19</sup>. The same surveys found that the percentage of youths that were 'ever smokers' was 14.3% in 2014 and 12.8% in 2018. Daily youth smoking has remained very low at 2.66% (2014) and 2.83% (2018). Daily vaping prevalence for 15 to 29-year olds is 2% according to data in Danish people's smoking habits 2019. Daily smoking prevalence for the same age group is 13%.

There is a real danger that focusing on youth use, without taking into account falling smoking rates or factoring in that the majority of young adults using safer nicotine products are already smokers, will lead to unnecessary overregulation that will be harmful to adult consumers of safer nicotine products. The main risk factor for a young person to become a smoker is whether family and friends smoke<sup>20</sup>. Making it easier for parents to stop smoking prevents their children from becoming smokers.

We appreciate that there are concerns about youth initiation but there is no evidence that non-smoking young people are becoming dependent on vaping nor that vaping is leading to young people smoking.

### ***3. Flavours are crucial to winning smokers over to safer products***

The Bill seeks to restrict e-liquid flavours, only tobacco and menthol flavours will remain on the market. The rationale given is that flavours "may entice children and young people into using tobacco products and electronic cigarettes". However, the evidence shows that flavours are not associated with youth smoking initiation but that flavours are essential for drawing adult smokers away from combustible cigarettes.

Vaping is successful at helping adult smokers - like so many of us - to quit. This is borne out by data from Belgium, France, Ireland and the UK<sup>21</sup>. Having a wide variety of flavours is intrinsic to the success of vaping products: the ability to tailor vaping to individual tastes plays a very important role in its effectiveness at drawing people away from smoking. The evidence in this area is clear, showing that whilst many people start vaping with a tobacco

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<sup>18</sup> Syddansk Universitet. Skolebørnsundersøgelsen 2014 [\[access\]](#)

<sup>19</sup> Sundhedsstyrelsen. Danskernes rygevaner 2019 [\[access\]](#)

<sup>20</sup> Leonardi-Bee J, Jere ML, Britton J. Exposure to parental and sibling smoking and the risk of smoking uptake in childhood and adolescence: a systematic review and meta-analysis. *Thorax* 2011;66:847-855 [\[access\]](#)

<sup>21</sup> Interview on Tobacco Products Directive: notes by ETHRA, pps 8-9 Impact of e-cigarettes on smoking cessation [\[access\]](#)

flavour, over time they gravitate towards fruit, dessert and sweet flavours<sup>22</sup>.

A recent study published in JAMA<sup>23</sup> concludes that “adults who began vaping non-tobacco flavored e-cigarettes were more likely to quit smoking than those who vaped tobacco flavors.” The same study also found that flavours are not associated with youth smoking initiation: “Relative to vaping tobacco flavors, vaping non tobacco-flavored e-cigarettes was not associated with increased youth smoking initiation but was associated with an increase in the odds of adult smoking cessation.”

Banning or restricting flavours will have a disastrous effect on smoking cessation, effectively removing the products responsible for huge reductions in smoking prevalence from the market. Non tobacco flavours help to disassociate smokers from the taste of tobacco and so lessen the chances of relapse to smoking. 77% of Danish vapers use non tobacco flavours, will these people go back to smoking when their flavours disappear from the legal market?<sup>24</sup>

The added danger with limiting or banning flavours is that consumers are then forced to use the grey market to obtain the product they need. This was the experience in Estonia, where a flavour ban and high taxation led to an explosion of grey-market products, reported to account for 62-80% of all sales<sup>25</sup>. In response, Estonia has recently amended its legislation.

States in the USA that have banned flavours have also seen thriving grey markets develop as ex-smokers seek out the only products that have successfully kept them smoke free. Black market sales of flavoured vaping products are reported<sup>26</sup> to be a regular occurrence in car parks around Long Island New York. Prohibition hasn't eliminated the product; it has simply driven it underground and criminalised those whose only crime is wanting to remain free from cigarette smoking.

There are also health risks associated with banning flavours, as consumers turn to unregulated products or mix their own e-liquids with food flavourings not suited for vaping. Oil based flavours in particular could present a significant health hazard. Inexperienced vapers driven to mix their own flavoured liquids may not be aware that e-liquid flavourings are water soluble, and in their desperation could add oil-based food flavourings to their liquids, without realising the inherent danger this poses.

A study<sup>27</sup> looking at the impacts of a flavour ban in California found that while flavour bans may reduce overall use of vapour products, they also may increase cigarette smoking.

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<sup>22</sup> Russell C, McKeganey N, Dickson T, Nides M. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J.* 2018 Jun 28;15(1):33 [\[access\]](#)

<sup>23</sup> Friedman AS, Xu SQ. Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and Cessation. *JAMA Netw open.* 2020 Jun 1;3(6): e203826. [\[access\]](#)

<sup>24</sup> Sundhedsstyrelsen. Danskernes rygevaner 2019 [\[access\]](#)

<sup>25</sup> Baltic Times. Estonian FinMin looking into prospect of lowering excise duty for e-cigarettes. 25 Nov 2019 [\[access\]](#)

<sup>26</sup> Filter. Vape Bans Are Creating a Thriving Illicit Market. 8 July 2020 [\[access\]](#)

<sup>27</sup> Yang Y, Lindblom EN, Salloum RG, Ward KD. The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults. *Addict Behav Rep.* 2020 Apr 1;11:100273 [\[access\]](#)

Comparing before and after the ban, cigarette smoking increased in 18 to 24-year olds from 27.4% to 37.1%.

#### **4. Combustion is the problem, not nicotine**

We are concerned by the Danish Ministry of Health's assertion that nicotine is highly addictive, and that nicotine can affect the further development of immature brains. In fact, use of e-cigarettes appears to be consistently associated with lower nicotine dependence than cigarette smoking<sup>28</sup> and there are no reports of people getting addicted to nicotine replacement therapies. We would be very interested in seeing the evidence behind the claim that nicotine affects human adolescent brain development, as to our knowledge no such evidence exists.

#### **5. Smokers have a right to accurate information about safer products**

Safer nicotine products are effective at helping adults to quit smoking, but it is crucial that smokers are aware of safer products and that accurate information on these safer alternatives to smoking is made accessible to them. It is particularly important that smokers are aware that non-combustible products are far less dangerous to health and that they would benefit from switching. The Bill's provisions with regards to restricting communications around safer products - standardised packaging, display restrictions and health warnings - are therefore very concerning to us.

The Tobacco Products Directive (TPD) mandates warnings to be placed on vaping products and the Bill seeks to apply those products to nicotine pouches too. The TPD mandated warnings are excessive and deter smokers from using safer products. The prominence (size, placement, colour and typeface) and the alarming wording suggest far greater risk than there is. The warnings are similar in style to those used on cigarettes, yet the risk, if any, is a small fraction of the risk of smoking. This tilts perceptions in favour of the more dangerous products. The warnings about nicotine have the effect of reinforcing the widespread misunderstanding that it is nicotine, not smoke, that is the most significant cause of harm. E-cigarettes and nicotine pouches only represent a fraction of the risk of combustible tobacco products and the warning labels should reflect this difference in risk.

Public Health England's 2018 evidence review<sup>29</sup> found that

*“vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know”.*

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<sup>28</sup> Shiffman S, Sembower MA. Dependence on e-cigarettes and cigarettes in a cross-sectional study of US adults [published online ahead of print, 2020 Mar 20]. *Addiction*. 2020;10.1111/add.15060 [\[access\]](#)

<sup>29</sup> Public Health England. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. February 2018 [\[access\]](#)

Safer nicotine products are novel products which are competing against a well-established incumbent - the combustible cigarette. Consumers need to know that the safer alternative products are out there. Vaping products in particular are a lot less simple to use than cigarettes and come in a very wide range of product types. Vape shops and specialist vendor websites have a crucial role in guiding smokers to find products which suit them and advising them on how to use the products. The Bill's display restrictions, standardised packaging requirements and advertising restrictions will prevent adult smokers from seeing and learning about the products, which are far less harmful to their health than combustible cigarettes. The mandatory warnings about nicotine massively overstate the risks and will prevent smokers from trying products which could have a positive impact on their health.

#### **6. Making safer products more expensive will deter smokers from switching**

We are also concerned that Denmark is set to make vaping much more expensive for consumers, as the increased product notification costs will be passed onto consumers and a tax on e-liquids is also in the pipeline. In our experience, price is a key factor for consumers in choosing to use safer products: people want to save money when they stop smoking. A recent study found that *"higher e-cigarette tax rates increase traditional cigarette use and reduce e-cigarette use"*<sup>30</sup>. Another study found that a 10% increase in e-cigarette prices caused traditional cigarette sales to jump by 11%<sup>31</sup>. Making safer products more expensive results in more smoking.

We see that access to Nicotine Replacement Therapy (NRT) will be widened under the Bill and so would like to remark here that the safer nicotine products we describe are all consumer products, bought at the individual consumer's expense - and at no cost to the state.

#### **Conclusion**

The Bill will increase smoking by making safer nicotine products less accessible, more expensive, and less appealing to adult smokers. 62% of Denmark's 786,000 smokers want to quit smoking<sup>32</sup> yet the Danish government wishes to restrict access to the most popular and successful smoking cessation tool available.

The Bill includes restrictions on the age of sale and requirements for robust age verification checks, we feel that this measure alone will achieve the objective of restricting youth access, without denying adult smokers these lifesaving alternatives.

We urge you to consider the welfare and health of Denmark's adult smokers and to listen to the experiences of consumers.

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<sup>30</sup> Pesko M.F, Courtemanche C.J, & Maclean J.C. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. *J Risk Uncertain*. 2020 [[access](#)]

<sup>31</sup> Georgia State University. Raising Taxes on e-Cigarettes Increases Cigarette Sales, New Research Shows Raising Taxes on e-Cigarettes Increases Cigarette Sales, New Research Shows. Georgia State News Hub. February 17, 2020 [[access](#)]

<sup>32</sup> Sundhedsstyrelsen. Danskernes rygevaner 2018 [[access](#)]

With kind regards, on behalf of the European consumers,



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