

**Iceland: Bill on an Act on electronic cigarettes and
refill containers for electronic cigarettes (Draft
transposition of the EUTPD2)
Fontem Ventures' response**



Introductory note

Fontem Ventures is dedicated to developing and growing a portfolio of innovative non-tobacco products including e-cigarettes and personal vaporisers, which we refer to throughout this document as “electronic vaping products” (EVPs). A fully owned subsidiary of Imperial Brands plc, we nevertheless operate at arm’s length from our parent company. Currently Fontem Ventures manufactures the EVP brand *blu* (available in France, Italy, UK and the U.S.).

Executive summary of Fontem Venture’s Comments

Fontem Ventures strongly supports evidence-based regulation of EVPs that is proportionate to their public health potential and clearly distinguishes them from all tobacco-containing products. We have the following opinion on the issues outlined in the Standing Committee’s terms of reference:

1. Comprehensive reviews of the scientific literature by independent organisations have reached the conclusion that **EVPs play a significant role in tobacco harm reduction**. Evidence-based regulation for the use and marketing of this category is crucial to ensuring that it becomes ever more legitimate and credible amongst smokers so that it can unfold its full public health potential.
2. A growing body of international clinical research concludes that **EVPs are significantly less harmful than smoking** and therefore have a huge public health potential. Any regulation should reflect this scientific evidence.
3. We can **learn a lot from other governments’ approaches** to regulating EVPs in a considered manner that **clearly distinguishes between tobacco products and non-tobacco products**.
4. A tailored rather than restrictive approach with regard to **product & manufacturing quality, safety standards, flavourings, marketing & advertising, sale & labelling and packaging** will help the category to grow and encourage smokers to switch to the vaping category, thereby directly contributing to tobacco harm reduction.

In sum, we would encourage the Icelandic Government towards an approach that allows nicotine-containing EVPs to be sold and consumed freely by adult smokers, but simultaneously ensures that products are manufactured to stringent quality standards, and are marketed and sold with controls in place that aim to prevent use by minors.

Fontem Ventures' comments on the Draft Proposal for the Bill on an Act on electronic cigarettes and refill containers for electronic cigarettes (from 17 July 2017)

SECTION I: General provisions

Article 3: Definitions

The definition of “advertisements” as “when a product or brand is presented to the public with the aim of increasing sales of the product, including any form of product promotion, displays in shops or in other places **or by discussion in the media** or by distribution of product samples to consumers” is unclear and leaves grey areas **in combination with Article 10**, which prohibits “advertisement of all types of electronic cigarettes”. There is no corresponding requirement in the EU Tobacco Products Directive (EUTPD). Instead, the EUTPD explicitly allows “publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market.” In order to support a coherent regulation within the European Economic Area (EEA), we recommend to not go further than the EUTPD. As it is stated in the recital of the directive (nr. 43) “disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition”.

The definition of “electronic cigarette” as “a product that can be used for the consumption of vapour, **irrespective of whether or not it contains nicotine** [...]” is also not in line with the EUTPD which clearly defines electronic cigarette as “a product that can be used for consumption of **nicotine-containing** vapour”. The definition in article 3 creates inconsistency with EUTPD in a number of articles that follow, most prominently in Article 4 (Warnings on packaging). There is no requirement for a health warning on non-nicotine e-liquids in the EUTPD. Although some other Member States (France, for instance) have captured non-nicotine products in some elements of their legislation transposing the EUTPD, e.g. reporting requirements, the objective behind doing so appears to be to ensure consistency and provide clear consumer information. Imposing an alarmist and unsubstantiated health warning on non-nicotine products, however, does not provide consumers with any further or clearer information, nor does it help achieve consistency in the legislation of nicotine-containing and nicotine-free e-cigarettes.

SECTION II: Importation, sale and marketing

Article 6: Age restrictions

Fontem supports this proposal: EVPs – irrespective of whether or not they contain nicotine – are intended for and should only be used by adult smokers and current EVPs users.

Article 10: Advertisements and visibility at points of sale

While we agree with the principle of regulating electronic cigarette advertising, and especially with minimising its targeting of and impact on children and adolescents, imposing a blanket ban on electronic cigarette advertising and restricting its visibility at points of sale is anti-competitive and disproportionate. In addition to our comments on Article 10 related to the

definition of “advertisements”, we want to highlight that the provision that “electronic cigarettes and refill containers shall **be placed in such a way at points of sale that they are not visible to costumers**” also exceeds stipulations of existing EU regulation without contributing to consumer protection. The EUTPD does not provide for such a restriction on points of sale and we recommend to closely comply with the directive to ensure a consistent regulatory framework across the EEA. Products should remain visible at points of sale in order to inform consumers appropriately and responsibly about the product before making a purchase decision.

In our view, marketing and advertising regulation must be proportionate to EVPs’ public health potential. Manufacturers should be able to clearly describe the characteristics and ingredients of their products at points of sale, including references to the fact EVPs do not contain tobacco. Given that many public health experts believe EVPs are significantly less harmful and “should be promoted as widely as possible”¹, it is important that regulatory frameworks support this goal. Manufacturers must be able to provide educational and scientifically legitimate information to smokers, not only so they can make informed decisions about the products available to them, but also so that vaping products can compete with established tobacco brands, thereby encouraging smokers to switch.

In Norway, an originally restrictive EVP regulation combined with a lack of market control has led to a flourishing black market and EVPs containing nicotine are sold online, despite the official ban. With regard to the Islandic proposal, fear is growing among Islandic EVP supply shop owners that the proposed regulation encourages a black market.² The Norwegian Government, as a consequence, is now moving fast towards an evidence-based approach towards EVPs that recognizes that EVPs are fundamentally different from all tobacco-containing products and that they should therefore be regulated via entirely separate frameworks from all tobacco-based products.

According to the Royal College of Physicians and Public Health England in the UK, “it is important to promote the use of e-cigarettes”³ and health agencies have “a responsibility to provide clear information on the evidence”⁴ to encourage complete smoking cessation and help prevent relapse to smoking.

These calls by public health groups to more heavily promote the use of EVPs are becoming all the more urgent as time progresses because consumer confidence in EVPs is declining and the market is stagnating, in large parts due to sensationalist media headlines, misinformation and misleading science that fails to compare the relative risks of vaping to smoking.

When UK NGO Action on Smoking and Health (ASH) conducted its annual YouGov survey in 2017, it found that perceptions of EVPs among smokers are getting worse - only 20% agreed that EVPs are ‘a lot less harmful’ than combustible tobacco, compared to 31% in 2015. In addition, the proportion adults who believe that EVPs are ‘as harmful’, or ‘more harmful’ than smoking nearly quadrupled from 2013 to 2017 from 7% to 26%.⁵ Further, the number of UK

¹ <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

² <https://grapevine.is/news/2017/02/20/fears-vape-law-could-create-black-market-for-vaping-oil/>

³ <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

⁴ <https://www.gov.uk/government/news/e-cigarettes-an-emerging-public-health-consensus>

⁵ <http://ash.org.uk/stopping-smoking/ash-briefing-on-electronic-cigarettes-2/>

vapers increased by just 4% from 2016 to 2017, compared to 86% in 2013, 62% in 2014, and 24% in 2015. Speaking about the findings, ASH said: “This is a communications challenge that needs to be met in order to reduce the harm caused by tobacco to smokers and those around them” and “it is very important smokers realize that vaping is much, much less harmful than smoking.”⁶

This trend is reflected in ongoing monitoring across the EU which shows Europeans’ perceptions of EVPs as ‘harmful’ increased from 27.1% in 2012 to 51.6% in 2014⁷ and 55% in 2017.⁸

While this does not detract from legitimate concerns about minors and non-smokers entering the category, year-on-year evidence from numerous studies, across multiple markets, shows that EVP use is overwhelmingly confined to current and former smokers. In light of this, a balance must be struck: EVP advertising and marketing should be permitted across multiple channels provided it only targets adult smokers, does not feature images, characters or flavour descriptors that appeal directly to minors, and only features individuals who are - and appear to be - over 25. Further, advertising should include a visible disclaimer advising that EVPs should only be used by people 18-years or over and that the product is not a tobacco product.

Therefore we think that the **prohibition of making EVPs visible at the point of sale** is overly restrictive and unfairly conflates EVPs with tobacco products. It is important that retailers are permitted to provide consumers with information about products at point of sale so as to ensure they are fully informed about the product they are purchasing.

Section III: Restrictions on the use of electronic cigarettes

Article 11: Restrictions on the use of electronic cigarettes

We would like to highlight that we support an approach to vaping in public places that fully respects youth protection (e.g. Article 11 b.). However, we disagree with wide-ranging restrictions on the use of EVPs as foreseen in all other provisions under Article 11. In our view, vaping should be permitted in public places but vapers should be courteous to those around them. There is strong scientific consensus that it is unjustified to apply smoke-free environment legislation to vaping products, since they are not tobacco products, do not contain tobacco, do not generate side-stream emissions, and pose no known air quality issue to bystanders.

It should be up to individual establishments and business owners to decide whether or not to permit the use of EVPs inside their premises. Numerous scientific studies, including the 2015 Public Health England report, all concluded that exposure to nicotine and other chemicals that may be present in exhaled EVP aerosol is negligible, with chemical analyses to date indicating that exhaled EVP aerosols are unlikely to warrant a concern to bystanders.

⁶ <http://ash.org.uk/media-and-news/press-releases-media-and-news/large-national-survey-finds-2-9-million-people-now-vape-in-britain-for-the-first-time-over-half-no-longer-smoke/>

⁷ Filippidis, F. T et al: “Two-year trends and predictors of e-cigarette use in 27 European Union member states”, *Tob Control*, 2016

⁸ <http://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2146>.

UK Government advice to employers encourages workplaces to adopt pro-vaping policies that make it as easy and convenient as possible for smokers to switch on the basis that there is “currently no evidence of harm from second-hand e-cigarette vapour.”⁹ This view is shared by the UK National Health Service¹⁰, Chartered Institute for Environmental Health¹¹, Cancer Research UK¹² and many others.

In France, following the government’s 2015 conclusion that “there is no evidence for passive vaping based on current scientific knowledge”¹³, in 2017 the Minister for Health and Social Services initiated a decree on indoor use of EVPs - signed by seven other Ministers – to allow vaping in enclosed work places, including stadiums, bars, hotels, restaurants and other venues.

Fontem Ventures’ own published scientific research shows that indoor vaping does not release chemicals or toxins into the air at levels that would pose an air quality issue to bystanders. Ambient air in a room in which Fontem EVPs were used continually for almost three hours still easily complied with indoor air quality regulations.¹⁴

Regulators should weigh up the existing scientific evidence on EVPs, and should take into account the fact that forcing vapers – the vast majority of whom are smokers trying to reduce or stop their tobacco consumption – to share a space with tobacco users could well undermine their attempts to quit smoking.

Section V: Education and awareness-raising

Article 18: Education and awareness-raising

We think that Article 18 that defines that “regular educational and awareness-raising activities take place regarding the **impact on health of using electronic cigarettes and the dangers involved in handling electronic cigarettes and refill containers**” is inaccurate, misleading and ignores scientific evidence. There is a growing body of independent scientific evidence to show that vaping is significantly less harmful than smoking.^{15,16,17} The mentioned report published by ASH in 2017 showed that one of the most common reasons for smokers not to try e-cigarettes was that they are “concerned they are not safe enough”¹⁸. The fact that this belief is widespread despite the growing evidence to the contrary means that governments must take great care in mandating educational and awareness raising activities regarding e-cigarettes, so as to ensure the much lower risk relative to smoking is properly

⁹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF

¹⁰ <http://www.nhs.uk/news/2015/08August/Pages/E-cigarettes-95-per-cent-less-harmful-than-smoking-says-report.aspx>

¹¹ <http://www.cieh.org/CIEH-comment-PHE-report-e-cigarettes-190815.html>

¹² <http://www.cancerresearchuk.org/about-us/cancer-news/press-release/2017-02-06-e-cigarettes-safer-than-smoking-says-long-term-study>

¹³ <http://www.assemblee-nationale.fr/14/amendements/2302/CION-SOC/AS1413.asp>

¹⁴ O’Connell, G et al: “An Assessment of Indoor Air Quality before, during and after Unrestricted Use of E-Cigarettes in a Small Room”, *Int J Environ Res Public Health*, 2015

¹⁵ A. McNeill et al on behalf of Public Health England: *E-cigarettes: an evidence update*, 2015

¹⁶ Belgium’s Superior Health Council and Health Ministry agreed that EVPs are a less harmful alternative to tobacco: *Tabacstop, Cigarette électronique: le nouvel avis du Conseil Supérieur de la Santé*, October 2015

¹⁷ The 2016 Cochrane Review found EVPs can help people quit smoking with no increased health risks from short- to mid-term (2 years’) use: H. Hartmann-Boyce et al., *Electronic cigarettes for smoking cessation*, September 2016

¹⁸ ASH UK, *Use of e-cigarettes among adults in Great Britain 2017* (Fig. 7), May 2017

understood. A fear-driven approach as suggested by Article 18 clearly undermines tobacco harm-reduction efforts.

We think that it would be more important to raise awareness among smokers regarding the potential of EVPs and would like to point out several positive examples of public policy measures in other European markets.

In countries where governments and public health bodies have invested sufficient time in researching and debating the science, most have concluded EVPs are significantly less harmful than smoking and can therefore contribute considerably to tobacco harm reduction. Importantly, these groups are focusing on the ‘relative risk’ of vaping compared to smoking cigarettes – a very important distinction because nearly all vapers are current or former tobacco users looking for an alternative.

In 2015, the UK Government agency Public Health England concluded that EVPs are 95% less harmful than smoking tobacco – a view supported by numerous other public health and tobacco-control groups in the UK, including the Royal College of Physicians, Action on Smoking and Health and Cancer Research UK.¹⁹ In August 2016, the UK Parliamentary Office of Science and Technology published a briefing for British Members of Parliament.²⁰ The three major conclusions from this briefing were that a growing body of evidence shows that EVPs are much less harmful than tobacco, there is evidence showing that EVPs can help smokers quit tobacco, and current evidence suggests that EVPs do not encourage tobacco smoking among non-smokers or children.

In France, the High Council on Public Health has endorsed EVPs as a cessation tool²¹, while in Belgium, the Superior Health Council and subsequently the Health Ministry agreed vaping is a less harmful alternative to smoking.^{22,23} Meanwhile, Norway’s Health Minister recently lifted a ban on EVP sales after recognizing that *“e-cigarettes have less damage potential than tobacco smoke”*.²⁴ The Royal Australian and New Zealand College of Psychiatrists has also endorsed EVPs.²⁵

At an international level, it should be noted that the World Health Organization (WHO), whilst concerned about certain aspects of EVPs, recognizes the potential role they can play in tobacco control. In a recent report, the WHO acknowledged that *“[i]f the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement”*.²⁶

¹⁹ <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>

²⁰ <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0533>

²¹ <http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=541>

²² <http://www.tabacstop.be/nouvelles/cigarette-lectronique-l-avis-du-conseil-sup-rieur-de-la-sant>

²³ http://www.lecho.be/economie_politique/belgique_federal/Maggie_De_Block_legalise_le_cigarette.9724879-3154.art?ckc=1

²⁴ <http://www.vapingpost.com/2016/12/26/ecigs-win-in-norway-but-at-what-price/>

²⁵ <http://www.dailytelegraph.com.au/news/nsw/the-royal-australian-and-new-zealand-college-of-psychiatrists-endorse-e-cigarettes/news-story/ec1c90c0ca6a21fa157d797418ca28ff>

²⁶ WHO FCTC Report on Electronic Nicotine Delivery Systems (“ENDS”) and Electronic Non-Nicotine Delivery Systems (“ENNDS”) to the seventh session of the Conference of the Parties at paragraph 5.

Large-scale reviews of scientific literature by independent organizations have reached similar conclusions: the 2016 Cochrane Review, for instance, found EVPs with nicotine can help people quit smoking with no increased health risks associated with short-to-medium term (two years) use.²⁷ Cochrane Reviews are systematic reviews of primary research in human health care and health policy, and are internationally recognized as the highest standard in evidence-based health care resources.

We acknowledge that EVPs have not been around long enough to generate epidemiological data, which looks at health impacts after decades of use, and we agree that more research is needed into the long-term effects of their use. However, the evidence to date indicates that the risks are highly likely to be much lower than continued cigarette smoking. This view is supported by several health bodies and NGOs. Estimations of long term public health impact of vaping have indicated significant reductions in smoking-attributable deaths²⁸, even when conservative assumptions were made for the relative health risk versus conventional cigarettes and for transitions between smoking, vaping and non-use.²⁹

Should you have any questions on Fontem Ventures' comments, please contact:

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²⁷ http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-and-are-they-safe-use-purpose

²⁸ Hill, A. and O. M. Camacho (2017). "A system dynamics modelling approach to assess the impact of launching a new nicotine product on population health outcomes." *Regul Toxicol Pharmacol* 86: 265-278.

²⁹ Levy, D. T., R. Borland, A. C. Villanti, R. Niaura, Z. Yuan, Y. Zhang, R. Meza, T. R. Holford, G. T. Fong, K. M. Cummings and D. B. Abrams (2017). "The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States." *Nicotine & Tobacco Research* 19(2): 149-159.