

**Fontem Ventures: Response to the Norwegian Ministry
of Health & Care Service**

**Consultative Paper on the Implementation of the
Tobacco Products Directive
(2014/40/EU)**



Introductory note

Fontem Ventures is dedicated to developing and growing a portfolio of innovative products including electronic cigarettes. A 100% subsidiary of Imperial Tobacco Group (ITG), we nevertheless operate at arm's length from our parent company and are focussed on non-tobacco opportunities only. Fontem Ventures markets the electronic cigarette (e-cigarette) brands blu (UK and US) and JAI (France and Italy).

Fontem Ventures supports sound, evidence-based, reasonable and proportionate regulation of e-cigarettes. Fontem Ventures wishes to provide input to the process of transposing the EUTPD II in Norway by herewith responding to the Consultative Paper on its proposed changes to the Harmful Effects of Tobacco Act. This response follows the structure of the Consultative Paper, addressing the transposition topic by topic.

This response complements a shorter paper which Fontem submitted at the end of December.

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Comments

1. Introduction

No comment.

2. Background Information

No comment.

3. Main Aspects of the Ministry's Proposal

No comment.

4. Tobacco Use in Norway

No comment.

5. Harmful Effects of Tobacco Use

No comment.

6. Electronic Cigarettes

The Consultative Paper highlights that, while initial studies indicate that e-cigarettes have less potential for harm than tobacco smoke, this has not yet been confirmed by long-term analyses. Fontem Ventures would point regulators towards the findings outlined in the Public Health England report¹, a review of over 180 peer-reviewed scientific studies, which concluded that in e-cigarettes “*most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that [e-cigarettes] are around 95% safer than smoking. This appears to remain a reasonable estimate.*”

6.1 Current Legislation

No comment.

6.2 The Tobacco Directive

No comment.

6.3 Pharmaceutical Legislation

No comment.

6.4 Medical Equipment Legislation

No comment.

6.5 Other Countries

Fontem Ventures notes that the Consultative Paper references several countries (e.g. Australia) which classify nicotine products as pharmaceuticals, regardless of whether they make medical claims or not.

The consequence of such a regulatory approach is that it effectively removes all e-cigarettes from the market (the first medical license for an e-cigarette was issued only early this year in the U.K.). As a result, smokers are unable to access e-cigarettes, which the public community has concluded offer a huge public health benefit¹, and so continue to use tobacco products;

¹ E-Cigarettes: An evidence update <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

and is also likely to force smokers to turn to disreputable or even illegal means of sale so as to obtain nicotine-containing e-cigarettes and refills. The Norwegian authorities should embody a regulatory approach aimed at preventing uptake of e-cigarettes by under 18s while encouraging tobacco smokers to shift to e-cigarettes that meet high quality and manufacturing standards.

6.6 The Prevalence of E-cigarettes

Fontem notes the Consultative Paper's reference to the growing prevalence e-cigarette use worldwide. Fontem would highlight that, while the number of smokers turning to e-cigarettes indeed seems to be growing, regular use among non- or never-smokers is "negligible"².

Fontem fully supports legislation that restricts the access of e-cigarettes among children and young people, and welcomes the fact that the sale of e-cigarettes to under-18s will be banned in Norway under Section 1.7 of the Harmful Effects of Tobacco Act. In addition, Fontem Ventures' marketing standard ensures that our advertising is of minimal attraction to under-18s, and we clearly mark on our products' packaging that they should not be sold to this age group. This is a stance shared by all responsible manufacturers. We would like to highlight that while figures suggest a small number of young people may have experimented with e-cigarettes, encouragingly continued or regular use among under-18s is almost non-existent among those who are not already tobacco users³.

Fontem is of the view that no e-cigarette flavour should be marketed or designed to appeal to anyone under the age of 18 e.g. bubble-gum, milkshake, cotton candy. Flavours have been found to play an important role in both perceived pleasure and the effort to reduce cigarette consumption of quit smoking in e-cigarette users.⁴ Given the uptake of e-cigarettes by youth is minimal, any restrictions to flavours used by adult e-cigarette users could have a negative impact on current e-cigarette users while no public health benefits would be observed in the young⁵.⁶ Fontem is also of the view that flavour variability should be maintained with any potential risk for anyone under the age of 18 being attracted to e-cigarettes sufficiently minimised by strictly prohibiting e-cigarette sales in this population group.

Fontem would also highlight that care must be taken when considering studies claiming to show that e-cigarette use is on the rise among young people: often studies classify respondents who report that they have tried e-cigarettes just once in the last 30 days as "current users" or similar. Such classifications skew the statistics and paint an unrepresentative and inaccurate picture of actual use among under-18s.

6.7 Health Risks

There are clear and substantial differences between e-cigarettes and tobacco products. As noted in our preliminary response to the Consultative Paper, provided at the end of 2015, misinterpretation of up-to-date science leads the authorities to propose wide-ranging bans on vaping in public places and to treat e-cigarettes in the same way as conventional tobacco products concerning their usage. These provisions stem from the assumed effects of potential bystander exposure to e-cigarette emissions.

² ASH Fact Sheet, May 2015, http://www.ash.org.uk/files/documents/ASH_891.pdf

³ ASH Fact Sheet, August 2015, http://www.ash.org.uk/files/documents/ASH_959.pdf

⁴ Farsalinos, K.E.; Romagna, G.; Tsiapras, D.; Kyrzopoulos, S.; Spyrou, A.; Voudris, V. Impact of flavour variability on electronic cigarette use experience: An internet survey. *International journal of environmental research and public health* 2013, 10, 7272-7282.

⁵ McNeill, A.; Brose, L.S.; Calder, R.; Hitchman, S.C.; Hajek, P.; McRobbie, H. *E-cigarettes: An evidence update*; Public Health England: 2015.

⁶ Moore, G.; Hewitt, G.; Evans, J.; Littlecott, H.J.; Holliday, J.; Ahmed, N.; Moore, L.; Murphy, S.; Fletcher, A. Electronic-cigarette use among young people in wales: Evidence from two cross-sectional surveys. *BMJ open* 2015, 5, e007072

It is stated that “*Present data indicates that nicotine levels in one's surroundings from passive exposure to e-cigarette aerosol leads to approximately the same high levels of nicotine in the blood of passive smokers as smokers of conventional cigarettes. This means one can expect the same harmful nicotine-related effects from passive exposure to e-cigarettes as from conventional cigarettes.*” E-cigarettes do not contain tobacco, do not burn, and do not smoulder unlike tobacco products. As a result, bystanders may only be exposed to aerosol exhaled by the consumer into the air but not to smoke. Numerous reviews of the scientific literature, including the Public Health England 2015 report, have concluded that exposure to nicotine and other chemicals that may be present in exhaled e-cigarette aerosol is negligible, below indoor air quality standards, with all chemical analyses to date indicating exhaled e-cigarettes aerosol does not warrant a concern to bystanders.^{7,8,9,10,11,12} Moreover, a recent study demonstrated that following a single puff on an e-cigarette, up to 99% of the nicotine inhaled is retained by the e-cigarette user and thus the nicotine concentration exhaled (to which a bystander may be exposed to) is negligible¹³.

In addition, the provisions state that “[...] *This does not mean that passive exposure to aerosol from e-cigarettes has a carcinogenic effect, but that this kind of passive use can influence the cardiovascular system, have a stimulating effect and contribute to dependency. Whether this has any effect on the reproductive system or the development of pulmonary functions will depend on the degree of exposure. More data and research will be necessary to say anything certain on this subject.*” To our knowledge, and again to the stated knowledge of Public Health England, there is no data in the scientific literature showing that “passive exposure” to aerosol from e-cigarettes has these effects.

6.8 Tobacco Policies and Public Health Considerations

6.8.1 Report from the Directorate for Health and Social Affairs

Fontem fully agrees with the Directorate for Health and Social Affairs' statement that: “*There is an obvious need to improve the way in which e-cigarette use is regulated.*”

This applies most notably to product quality and standards, which vary across the sector. Although the entry into force of the EUTPDII will harmonise some aspects of technical and product standards, up until now only a small number of voluntary measures (for instance the BSI and AFNOR standards in the UK and France, respectively) have been in operation. Fontem is of the view that the Norwegian authorities should seize this opportunity to introduce positive measures that would drive up industry standards, build confidence in the e-cigarette category and remove less reputable e-cigarette vendors and products from the market. To that end, Fontem welcomes efforts on the part of governments and authorities to set binding and sector-

⁷ McNeill, A.; Etter, J.F.; Farsalinos, K.; Hajek, P.; le Houezec, J.; McRobbie, H. A critique of a who-commissioned report and associated article on electronic cigarettes. *Addiction* (Abingdon, England) 2014.

⁸ McNeill, A.; Brose, L.S.; Calder, R.; Hitchman, S.C.; Hajek, P.; McRobbie, H. E-cigarettes: An evidence update; Public Health England: 2015.

⁹ Burstyn, I. Peering through the mist: Systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC public health* 2014, 14, 18.

¹⁰ Saitta, D.; Ferro, G.A.; Polosa, R. Achieving appropriate regulations for electronic cigarettes. *Therapeutic advances in chronic disease* 2014, 5, 50-61.

¹¹ O'Connell, G.; Colard, S.; Cahours, X.; Pritchard, J.D. An assessment of indoor air quality before, during and after unrestricted use of e-cigarettes in a small room. *International journal of environmental research and public health* 2015, 12, 4889-4907.

¹² Colard, S.; O'Connell, G.; Verron, T.; Cahours, X.; Pritchard, J.D. Electronic cigarettes and indoor air quality: A simple approach to modeling potential bystander exposures to nicotine. *International journal of environmental research and public health* 2015, 12, 282-299.

¹³ O'Connell, G.; Colard, S.; Breiev, K.; Sulzer, P.; Biel, S.S.; Cahours, X.; Pritchard, J.D.; Burseg, K.M.M. An experimental method to determine the concentration of nicotine in exhaled breath and its retention rate following use of an electronic cigarette. *J Environ Anal Chem* 2015, 2.

wide standardization requirements to protect consumers from the risks posed by poor quality products.

Fontem also shares the Directorate's belief in the importance of regulation that minimises the potential attraction or appeal of e-cigarettes to young people. As already noted, Fontem is already addressing this by restricting its marketing and sales activities specifically towards the over-18 smokers.

Regarding the Directorate's notes on monitoring the interplay between nicotine and tobacco use, Fontem would draw attention to the fact that to date, no credible evidence has been found to suggest either a "gateway" or "renormalisation" effect is occurring in any country where e-cigarette use is increasing in popularity. Indeed, there is no scientific evidence that show e-cigarettes are undermining the long-term decline in tobacco smoking among adults and youth; they may in fact be contributing to it¹⁴.

An estimated 2.6 million adults in the UK currently use e-cigarettes with 60% current smokers and 40% ex-smokers¹⁵. Despite some very limited experimentation among never smokers, regular use among never smokers is extremely rare and estimated around 0.2%¹⁶. Interestingly, a recent scientific study by academics at the University of Cardiff studying e-cigarette use in young people in Wales (funded by the Welsh Government's Public Health Division) concluded that: "*the very low prevalence of regular use [...] suggests that e-cigarettes were unlikely to be making a significant direct contribution to adolescent nicotine addiction*"¹⁷. This is further scientific evidence that suggests e-cigarettes are not re-normalising the act of smoking or serving as a "gateway" to traditional tobacco products, particularly among youngsters.

Several behavioural and social factors further reduce the likelihood of e-cigarettes re-normalising tobacco use. First is the fact that most e-cigarette users do not wish to be associated with smoking and choose e-cigarettes that do not resemble conventional tobacco products. Moreover, the use of e-cigarettes is likely to contribute further to the de-normalisation of smoking by reducing the number of smoking role models, reducing frequency of public smoking and by providing a role model for the rejection of smoking. For that reason, e-cigarettes are likely to act as a gateway *out* of tobacco use¹⁸. As e-cigarettes are not a gateway *to* smoking but a gateway *from* smoking, heavy regulation by restricting access to e-cigarettes risks encouraging continued use of tobacco smoking¹⁹.

¹⁴ McNeill, A.; Brose, L.S.; Calder, R.; Hitchman, S.C.; Hajek, P.; McRobbie, H. E-cigarettes: An evidence update; Public Health England: 2015

¹⁵ ASH. Electronic cigarettes (also known as vapourisers).

http://www.ash.org.uk/files/documents/ASH_715.pdf (10 August 2015)

¹⁶ 9 McNeill, A.; Brose, L.S.; Calder, R.; Hitchman, S.C.; Hajek, P.; McRobbie, H. E-cigarettes: An evidence update; Public Health England: 2015.

¹⁷ Moore, G.; Hewitt, G.; Evans, J.; Littlecott, H.J.; Holliday, J.; Ahmed, N.; Moore, L.; Murphy, S.; Fletcher, A. Electronic-cigarette use among young people in wales: Evidence from two cross-sectional surveys. *BMJ open* 2015, 5, e007072.

¹⁸ Polosa R., Caponnetto P. (2013) Time for evidence-based e-cigarette regulation. *Lancet Oncol* 14: e582-e583

¹⁹ Saitta, D.; Ferro, G.A.; Polosa, R. Achieving appropriate regulations for electronic cigarettes. *Therapeutic advances in chronic disease* 2014, 5, 50-61.

6.8.2 The SIRUS Report

The SIRUS report listed the potential arguments against the benefits of e-cigarettes. Fontem has reviewed these arguments and provided its comments below.

- ***“If very many more non-smokers than smokers/potential smokers would begin to use e-cigarettes”***

All existing data - including the figures which the Norwegian document cite - shows that this is simply not the case: the overwhelming majority of e-cigarette users are current or ex-smokers.

- ***“If e-cigarettes deterred or postponed the efforts of very many people to quit smoking who otherwise would had managed to stop”***

Existing data shows that this is not true - the overwhelming majority of scientific evidence also show e-cigarettes are not re-normalising the act of smoking or serving as a “gateway” to tobacco products.

- ***“If experimenting with e-cigarettes would be a causal reason for subsequently starting to smoke tobacco among very many older children”***

Concerns have been expressed about e-cigarette use by youngsters or by never smokers, with e-cigarettes becoming a gateway to smoking or becoming a new form of addiction. However, such concerns are unsubstantiated by existing data that e-cigarette use by youngsters is virtually non-existent unless they are already smokers^{20, 21, 22}.

- ***“If double use (e-cigarettes and conventional cigarettes) would lead to unique harm, side effects and/or increase the risk of secondary harm or damage beyond the risks that already exist from tobacco smoking”***

Following a review of the scientific literature, public health experts have concluded e-cigarettes are 95% safer than tobacco cigarettes²³. A recent study found “dual use” (of e-cigarettes and tobacco cigarettes) is not a negative consequence of e-cigarette use, but a positive outcome that could well stand on a pathway to eventual smoking cessation²⁴. The most important study findings were of the dual users: 64% reported having reduced their cigarette consumption; 56% had cut their cigarette consumption by 50% or more; 81% reported having quit smoking for a period of at least one week; 70% reported the intention to quit smoking within six months; 88% reported that they planned to cut their cigarette consumption by at least half in the next six months; 63% predicted that they would quit smoking completely within six months, and another 27% predicted that they would cut their cigarette consumption within six months²³. Another study reported similar positive outcomes of dual use²⁵. Interestingly, a recent clinical study found e-cigarette use “*may*

²⁰ Centers for Disease Control and Prevention (2013) Notes from the field: electronic cigarette use among middle and high school students - United States, 2011-2012. MMWR Morb Mortal Wkly Rep 62: 729-730

²¹ Dockrell M., Morison R., Bauld L., McNeill A. (2013) E-cigarettes: prevalence and attitudes in Great Britain. Nicotine Tob Res 23 May 2013.

²² Camengaa D., Delmericob J., Kongc G., Cavallo D., Hyland A., Cummings K., et al. (2014) Trends in use of electronic nicotine delivery systems by adolescents. Addict Behav 39: 338-340

²³ McNeill, A.; Brose, L.S.; Calder, R.; Hitchman, S.C.; Hajek, P.; McRobbie, H. E-cigarettes: An evidence update; Public Health England: 2015

²⁴ Russell C, McKeganey N, Hamilton-Barclay T. An online survey of 5,000 vapers' perceptions and experiences of using electronic cigarettes as an aid to smoking cessation. Glasgow, Scotland UK: Centre for Drug Misuse Research. Presented at the Tobacco Science Research Conference, September 22, 2015

²⁵ Collins and Stotesbury (2015) https://gfn.net.co/downloads/2015/posters/103_-_Andrew_Collins.pdf

*reduce harm even in smokers who continue to smoke*²⁶ thus showing the great potential e-cigarettes offer to smokers that do continue to smoke²⁶

6.9 The World Health Organization's Report and Recommendations

In Fontem's view, the World Health Organization's report and recommendations are disproportionately harsh towards e-cigarettes and fail to acknowledge the clear and substantial differences between e-cigarettes and conventional tobacco products. The WHO report and recommendations also fail to take into account the growing body of evidence for a more favourable regulatory regime for e-cigarette products. Fontem is not alone in holding this view; we would point the Norwegian government towards the open letter signed by over 50 independent leading health specialists, which was published ahead of the Framework Convention on Tobacco Control (FCTC) Sixth Conference of the Parties in 2014²⁷. The letter concludes that: *"The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century - perhaps saving hundreds of millions of lives."*

Chief among the signatories' recommendations are:

- *Tobacco harm reduction is part of the solution, not part of the problem.*
- *Tobacco harm reduction policies should be evidence-based and proportionate to risk, and give due weight to the significant reductions in risk that are achieved when a smoker switches to a low risk nicotine product.*
- *Targets and indicators for reduction of tobacco consumption should be aligned with the ultimate goal of reducing disease and premature death, not nicotine use per se, and therefore focus primarily on reducing smoking.*
- *It would be counterproductive and potentially harmful to include reduction of low-risk nicotine products, such as e-cigarettes, within [targets for the Non-Communicable Disease framework]: instead these products should have an important role in meeting the targets.*
- *[...] It would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products.*
- *It is counterproductive to ban the advertising of e-cigarettes and other low risk alternatives to smoking.*
- *It is inappropriate to apply legislation designed to protect bystanders or workers from tobacco smoke to vapour products. There is no evidence at present of material risk to health from vapour emitted from e-cigarettes.*

6.10 The Ministry's Assessment as to Whether the Current Norwegian Ban Should be Reverted

Although e-cigarettes do not contain tobacco, Fontem Ventures welcomes the Ministry's assessment that "regulating e-cigarettes according to the Tobacco Directive would be the most appropriate approach". Reasonable and proportionate regulation - particularly with regard to sales and advertising, as well as quality standards - will enable smokers to access an attractive alternative to tobacco, while at the same time minimizing use among young people and non-smokers.

Fontem is disappointed, however, that the Ministry "proposes that e-cigarette use should be encompassed by the general ban on smoking as laid out in sections 25, 26 and 27 of the Harmful Effects of Tobacco Act". Please see our comments on section 6.20 for further details.

²⁶ McRobbie, H.; Phillips, A.; Goniewicz, M.L.; Smith, K.M.; Knight-West, O.; Przulj, D.; Hajek, P. Effects of switching to electronic cigarettes with and without concurrent smoking on exposure to nicotine, carbon monoxide, and acrolein. *Cancer Prevention Research* 2015, 8, 873-878.

²⁷ Statement from specialists in nicotine science and public health policy, May 2014, <https://nicotinepolicy.net/documents/letters/MargaretChan.pdf>

6.11 Definition of E-cigarette (ref. changes to Section 2 of the Harmful Effects of Tobacco Act)

Fontem agrees with the Ministry's proposal.

6.12 Registration Requirements (ref. new Chapter 6 A-1 & changes to Section 38 of the Harmful Effects of Tobacco Act)

Fontem Ventures agrees with the Ministry's proposal, but would highlight the importance of ensuring that trade secrets are protected during the registration process, especially during stages where information contained in registration or notification submissions is made publicly available. The e-cigarette category is nascent and developing, and its success depends on manufacturers' ability to harness innovation to constantly improve and update their offering, and the provision of the information described in the registration prior to the placing on the market of those products poses a real risk for new product launches for which every element of information would be considered confidential. A robust mechanism should be defined to prevent the information from entering the public domain before the launch of the product to consumers.

Once a product has been launched we would consider it appropriate for information which is considered commercially sensitive or proprietary information, and therefore a trade secret, to be made available in the public domain. This can best be facilitated through the use of a separate reporting format which would not need the Norwegian Medicines Agency to interpret or translate what information could be disseminated into the public domain.

Furthermore, Fontem Ventures has established confidentiality agreements with all suppliers to protect their propriety information, covering disclosure to authorities for regulatory purposes but not allowing dissemination into the public domain.

Fontem Ventures would therefore recommend the use of a separate public reporting format to protect proprietary third party information and to protect the identity and amounts of any individual flavouring ingredient in the liquid at a concentration of less than 0.1% w/w presented as a generic term 'Flavours'.

Fontem would also recommend that fees are proportionate and justified, so as to ensure that manufacturers are not simply "priced out" of the market.

6.13 Quality and Safety Requirements (ref. new Chapter 6 A-1 of the Harmful Effects of Tobacco Act)

Fontem agrees with the Ministry's assessment that poor quality and leaky e-cigarettes may pose a safety risk. We believe that the refill standards currently being finalized by the European Commission will contribute significantly to reducing the availability of low quality products to consumers.

Fontem also agrees that it is important to monitor and control the content of e-cigarettes. However, we would caution that the Medicines Agency ensure that trade secrets are adequately protected during any control processes, particularly publication of their findings.

We would also advise caution in any subsequent measures taken with regard to controlling flavourings - flavour is a key component in ensuring e-cigarettes are attractive to smokers (see Section 6.6). We would strongly urge the Ministry to avoid putting in place any wide-ranging or blanket flavouring restrictions, since this would curb innovation and jeopardise the market viability of e-cigarettes and appeal to smokers

6.14 Requirements about Instructions for Use

Fontem agrees with the Ministry's proposal.

6.15 Labelling and Packaging Requirements (ref. new Chapter 6 A-3 of the Harmful Effects of Tobacco Act)

There is a body of evidence - some of which has been published since the adoption of EUTPDII - which suggests that nicotine, outside of tobacco smoke, is not in itself 'highly' addictive, evidence which the Norwegian authorities may wish to consider. For example, a recent scientific study found "*E-cigarettes may be as or less addictive than nicotine gums, which themselves are not very addictive*"²⁸

6.16 Handling Harmful and Adverse Effects (ref. new Chapter 6 A-4 of the Harmful Effects of Tobacco Act)

Fontem agrees that manufacturers have a responsibility towards ensuring the highest possible levels of safety for their consumers. We therefore consider collecting information on suspected adverse effects of e-cigarettes, and taking appropriate action if products are inadequately safe, to be an important part of good manufacturers' obligations.

6.17 Market Monitoring (ref. new Chapter 6 A-5 of the Harmful Effects of Tobacco Act)

Fontem agrees that it is important to monitor use of e-cigarettes among different users and demographics, particularly with regards to a so-called "gateway". As mentioned above, current data suggests that e-cigarettes are likely to be acting as a gateway out of tobacco use.

6.18 Remote Sales

See comments on chapter 13.

6.19 Supplemental Regulations

Advertising ban (ref. changes to Sections 22, 23 & 24 of the Harmful Effects of Tobacco Act)

Fontem Ventures strongly opposes the proposed strict ban on advertising, notably regarding the following restrictions:

- The ban on domestic sponsorship (ref. changes to Section 23 of the Harmful Effects of Tobacco Act)
- The limitations to webpage design ensuing from simply extending Section 22 of the Harmful Effects of Tobacco Act to cover "tobacco substitutes"
- The visibility prohibition (ref. changes to Section 24 of the Harmful Effects of Tobacco Act)

Fontem Ventures supports the responsible advertising and marketing of e-cigarettes. As public health experts have concluded that vaping products are 95% safer than tobacco, then vaping must be promoted over conventional cigarettes, in a way that allows vaping brands to compete with well-established tobacco brands. To do this, the Norwegian authorities must ensure smokers have access to information that will encourage them to switch.

As noted previously in this response, the overwhelming majority of scientific evidence shows e-cigarettes are not re-normalising the act of smoking or serving as a "gateway" to traditional tobacco products, in particular amongst under 18s. There is no scientific evidence that shows e-cigarettes are undermining the long-term decline in tobacco smoking among adults and youth and they may in fact be contributing to it.

²⁸ "Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes" by Etter and Eissenberg 2015 (<http://www.ncbi.nlm.nih.gov/pubmed/25561385>)

Vaping products are a product of choice for adults - and should never be sold or targeted to minors. Therefore marketing and advertising of vaping products should be socially responsible and only sold to adults - Fontem Ventures has leading marketing standards. We believe that strict marketing standards should apply for the whole industry, but that responsible and strictly monitored advertising should be allowed to increase the rate of smokers becoming aware of e-cigarettes and switching.

Banning advertising from the very outset runs the risk of protecting existing conventional tobacco habits. Transition periods, in which companies that have received market authorisation are allowed limited advertising to establish brands and appeal to smokers should be established as an absolute minimum.

Special issues related to self-service purchases (ref. changes to Section 18 of the Harmful Effects of Tobacco Act)

Fontem Ventures would recommend that e-cigarettes are available for self-service purchase when such vending outlets are equipped with an age-verification system, or are located in access-restricted over-18 venues. This helps widen e-cigarettes' access - which is important to establish them as a viable alternative to tobacco products, given that they are a relatively new product category.

Age limits (ref. Item 48. Section 11 of the Harmful Effects of Tobacco Act)

Fontem Ventures welcomes the ban on selling e-cigarettes and refill containers to under-18s, since such products are intended for adult smokers and former smokers only.

Prohibitions against free distribution and discount sales (ref. Section 20 & changes to Section 21 of the Harmful Effects of Tobacco Act)

Fontem Ventures opposes the proposed bans on free distribution (to adults) of e-cigarettes and the selling e-cigarettes at discount prices. Such a ban will prevent retailers from raising awareness of e-cigarettes, which in turn will lead to a much lower uptake rate among smokers.

Consumer testing (ref. changes to Section 34 of the Harmful Effects of Tobacco Act)

Fontem would advise against implementing "a ban on consumer testing". Such an action prevents manufacturers from maximising the attractiveness of e-cigarettes to smokers - for instance by curtailing their ability to find out what adult smokers' preferred device styles, nicotine strengths or flavours are - which in turn means products are less likely to prevent smokers from returning to tobacco use. Moreover, a ban on consumer testing for e-cigarettes will prevent scientists from carrying out accurate and representative studies into e-cigarettes, inhibiting their ability to draw firm conclusions in the future.

[6.20 Inclusion of E-cigarette in the Smoking Prohibition \(ref. Section 29 A of the Harmful Effects of Tobacco Act\)](#)

As noted in Fontem's response to section 6.7, misinterpretation of up-to-date science leads the authorities to propose wide-ranging bans on vaping in public places and to treat e-cigarettes in the same way as conventional tobacco products concerning their usage.

There is no scientific-based justification for the inclusion of e-cigarettes in existing smoke-free regulations in Norway. A recent review of the scientific literature found the use of e-cigarettes in areas where smoking is banned "*may encourage smokers to make the switch to a product that could save their health and their lives, thereby helping to de-normalise smoking by*

reducing the overall number of smokers".²⁹ By banning e-cigarette use in public and work places in Norway, the authorities are forcing e-cigarette consumers to use their products in designated smoking areas where e-cigarette users are exposed to "second-hand smoke". The public health community has previously concluded "second-hand smoke" is a cause of smoking-related disease and there is no safe level of exposure to tobacco smoke³⁰.

Fontem Ventures are also of the view that effectively extending a tobacco ban to include e-cigarettes only serves to further stigmatise adult e-cigarette users and as such we consider it to be an unjustified restriction on the freedom of individuals to use a product with the greatest potential for those seeking an alternative to tobacco. In principle, Fontem does not believe there should be any bans in non-enclosed spaces, except on actual school premises or other premises whose purpose is expressly child-oriented.

6.21 Supervision

Please see above for Fontem's comments on a prohibition on public use of e-cigarettes.

7. Emissions Levels from Tobacco Smoking

No comment; Fontem's interpretation is that e-cigarettes are not subject to these requirements, given that they are not tobacco products and are not "smoked".

8. Measurement Methods for Emissions from Tobacco Smoking

No comment; Fontem's interpretation is that e-cigarettes are not subject to these requirements, given that they are not tobacco products and are not "smoked".

9. Reporting Emissions and Ingredients

No comment; Fontem's interpretation is that e-cigarettes are not subject to these requirements, given that they are not tobacco products and are not "smoked".

10. Extended Reporting Obligations for Certain Additives

No comment; Fontem's interpretation is that e-cigarettes are not subject to these requirements, given that they are not tobacco products.

11. Ingredients

No comment.

12. Labelling and Packaging

No comment; Fontem's interpretation is that e-cigarettes are not subject to these requirements, given that they are not tobacco products.

²⁹ Saitta, D.; Ferro, G.A.; Polosa, R. Achieving appropriate regulations for electronic cigarettes. *Therapeutic advances in chronic disease* 2014, 5, 50-61

³⁰ WHO. Only 100% smoke-free environments adequately protect from dangers of second-hand smoke. <http://www.who.int/mediacentre/news/releases/2007/pr26/en/> (10 August 2015)

13. Remote Sales Across National Borders (ref. changes to Section 3 A-2 through A-7 of the Harmful Effects of Tobacco Act)

Fontem Ventures welcomes the Ministry's stance of permitting but regulating cross-border distance sales. This will widen consumer access, while still ensuring that products comply with Norwegian regulations and standards.

The Ministry proposes altering the Harmful Effects of Tobacco Act to include a provision to require retail locations that are established outside Norway to appoint a natural person in Norway. In principle, we would advocate that the government limits administrative burdens for manufacturers, so as to avoid creating unnecessary barriers to entry. At the same time, however, we also recognize that clarity on legislation and enforcement is very important for the e-cigarette category, since it is very new and not yet aligned in terms of product and retailing standards.

We accept, therefore, that manufacturers' nomination of an individual to verify product compliance would help provide this clarity. However, so as to mitigate the potential administrative or economic burdens of this process, we would suggest that the Government grant producers or manufacturers some leeway in nominating the aforementioned individual (e.g. subsidiaries should be able to nominate representatives from their parent companies and vice-versa).

Fontem Ventures supports the Ministry's proposal regarding age-verification requirements for retailers offering remote sales of e-cigarettes.

14. New Tobacco Products (ref. new Chapter 6 A-7 of the Harmful Effects of Tobacco Act)

Fontem understands that e-cigarettes and their refill containers would not fall under the definition of a "new nicotine product", given that they are already defined separately by the EUTPDII and subject to their own separate set of legislation.

Fontem would consider "novel" or "new" tobacco products to include, but not limited to, tobacco products which are reported to "heat" rather than "burn" tobacco. Certain manufacturers are trying to position these "heated tobacco" (so-called "heat-not-burn") products as somehow analogous with e-cigarettes, Fontem Ventures is fundamentally opposed to any regulation, standard, code or excise category that would have the effect of linking e-cigarettes with tobacco-containing products. We believe regulation should strictly separate and group all products that contain tobacco, both traditional and 'novel' tobacco products, separately from products like e-cigarettes that do not contain tobacco.

Subsequently, we support the proposal to subject novel/new tobacco products, including but not limited to "heated tobacco", to an approval/authorisation scheme.

15. Herb-based Smoking Products

No comment; Fontem Ventures' interpretation is that e-cigarettes are not subject to these requirements, given that they are not herbal smoking products.

16. Exceptions from the Prohibition against Visible Displays of Tobacco Products etc.

The consultative paper notes that: *"Starting 1 January 2010 a new provision will be incorporated in Section 5 (currently in Section 24) of the Harmful Effects of Tobacco Act that prohibits visible displays of tobacco products. A major statutory revision was carried out in 2012, in which the prohibition would be extended to also include tobacco imitations and*

substitutes; ref. Section 24 second paragraph of the Act. The latter provision came into force on 1 July 2013.”

Fontem Ventures would recommend that e-cigarettes are exempt from this prohibition, given that in light of evidence such as the Public Health England 2015 report, it seems desirable to make them readily available and visible as a tobacco alternative. Since they are a very new product category, however, there is currently lower consumer awareness of their availability, which would be further stymied by a ban on their visible display. Moreover, it is important that e-cigarettes are able to compete with established tobacco brands.

17. Financial and administrative consequences

Fees and charges

Fontem Ventures believes that any fees charged to industry should be justified, proportionate and rational. The fees proposed by Denmark are notably higher than those proposed by other Member States³¹, and we would strongly advise the Ministry against using them as a guide in setting fees, as they risk constituting a serious barrier to entry for many manufacturers.

³¹ The UK, for instance, has proposed a notification fee of £220 for a new product and an ongoing annual periodic fee for service thereafter of £60, plus a fee of £110 for processing each notification for modification to an existing product.