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

Høring om forslag til endringer i tobakksforskriftene og ny forskrift om elektroniske sigaretter

Introductory note

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

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 consultation on proposed changes to the tobacco regulations and new regulations on electronic cigarettes ("Høring om forslag til endringer i tobakksforskriftene og ny forskrift om elektroniske sigaretter"). This response follows the structure of the consultation memorandum, addressing the memorandum topic by topic.

This response complements papers which Fontem submitted in December 2015 and January 2016.

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Comments

1. Introduction

Fontem Ventures welcomes the revoking of the prohibition on new nicotine products. With regard to the note that "*After the consultation, the Ministry will […] assess whether the regulations should rather be merged into one common tobacco regulation*", we would urge the Ministry to note that e-cigarettes do not contain any tobacco and therefore should not be placed in the same regulatory category as tobacco products.

We would call for the Ministry to consider e-cigarette regulation in the context of the growing scientific evidence that e-cigarettes are significantly less harmful to users than conventional tobacco cigarettes and have significant potential in reducing tobacco consumption.

In countries where regulators and public health bodies have invested sufficient time researching the science around e-cigarette use, many conclude that e-cigarettes are significantly less harmful than conventional tobacco cigarettes and therefore can play a key role in reducing tobacco-related disease worldwide. A snapshot of up-to-date science includes the following:

- The most recent 2016 Cochrane Review of existing published studies found (i) use of nicotine-containing e-cigarettes increased users' chances of stopping smoking; (ii) short- to mid-term (up to two years) use of e-cigarettes does not have serious side effects; and (iii) in some cases, switching to e-cigarettes leads to changes in blood and breath that are consistent with changes you would see in people who gave up smoking all together.[1]
- Recent clinical trials have shown that smokers who partially or completely switch to e-cigarettes significantly reduce their exposure to harmful and potentially harmful constituents found in tobacco smoke that are reported by FDA to contribute significantly to smoking-associated disease risks.[2,3]
- After a comprehensive review of the scientific literature, UK government agency Public Health England found e-cigarettes are around 95% less harmful than smoked tobacco[4] – a view supported by Action on Smoking and Health UK and Cancer Research UK.[5]
- France's High Council on Public Health has endorsed e-cigarettes as a cessation tool[6], while Belgium's Superior Health Council and Health Ministry agree e-cigarettes are a less harmful alternative to tobacco.[7,8]

All these groups are moving towards a broad scientific consensus that use of e-cigarettes, when compared to smoking, could present a critical tool in global tobacco harm reduction.

This is reinforced by figures showing that nicotine-containing e-cigarettes are almost exclusively used by current or ex-smokers[9]. Recent studies have reported that using e-cigarettes have helped 6.1 million people across the European Union to quit smoking and another 9.2 million reduce their tobacco intake.[10]

[1] J. Hartmann-Boyce et al: "Electronic cigarettes for smoking cessation", *Cochrane Database of Systematic Reviews*, Sept. 2016
[2] O'Connell et al: "Reductions in biomarkers of exposure (BoE) to harmful or potentially harmful constituents (HPHCs) following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers". *Toxicol Mech Methods*, 2016
[3] M. Goniewicz, et al: "Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study", *Nicotine & Tobacco Research*, June 2016
[4] A. McNeill et al on behalf of Public Health England: "E-cigarettes: an evidence update", 2015
[5] https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review
[6] http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=541
[7] http://www.tabacstop.be/nouvelles/cigarette-lectronique-l-avis-du-conseil-sup-rieur-de-la-sant
[8] http://www.lecho.be/economie_politique/belgique_federal/Maggie_De_Block_legalise_l_e_cigarette.9724879-3154.art?ckc=1
[9] Action on Smoking and Health, May 2016: "*Use of electronic cigarettes among adults in Great Britain*"
[10] K. Farsalinos et al: "*Electronic cigarette use in the European Union*". *Addiction*, 2016.

2. Main content of the Ministry's proposal

Fontem Ventures welcomes the proposed termination of the prohibition on e-cigarettes. We believe that proportionate regulation is important to the development of the category, but would stress that manufacturers must have freedom to create products that are attractive and affordable, and that smokers must be able to buy e-cigarettes from a range of sales points and to use them in public places. Blanket bans on advertising and use of e-cigarettes in public places, as outlined in this section and elaborated in our comments on section 3.2 and 3.3.2 respectively, are disproportionate, anti-competitive and unfairly conflate e-cigarettes with tobacco products.

3. Regulation on electronic cigarettes

3.1 Background

No comments.

3.2 Governing law

Fontem Ventures would strongly dispute e-cigarettes' inclusion in tobacco prohibitions and limitations:

Advertising prohibition: E-cigarettes should not be subject to blanket prohibitions on advertising and sponsorship, firstly because imposing tobacco-style advertising restrictions on e-cigarettes conflates public perception of e-cigarettes and tobacco products. This is unfair, inaccurate and anti-competitive as e-cigarettes do not contain any tobacco. Moreover, the ability to advertise and market e-cigarettes is vital in providing adult smokers with educational and scientifically legitimate information about the alternatives to tobacco that are available to them. In addition, permitting e-cigarette advertising is necessary to ensure that e-cigarettes can compete with well-established tobacco brands and nicotine replacement therapy products, so as to encourage smokers to switch. However, qualitative controls on e-cigarette advertising should be enacted to limit potential appeal to children and adolescents. For example, advertising should not feature characters, themes or tropes that target or primarily appeal to under-18s.[11]

Prohibition against free distribution: Such a ban would undermine retailers' efforts to raise awareness of e-cigarettes and could discourage current smokers from trying e-cigarettes to find the best product for their needs. This will in turn lead to a much lower uptake rate among smokers. This effect is undesirable in light of the growing evidence and consensus that e-cigarettes are less harmful than smoking.

However, we agree with the Ministry's stance that e-cigarettes should be used by adult smokers only. Consequently, we support the enactment on a prohibition on their sale to minors.

3.3 The Ministry's proposition

No comment.

3.3.1 Purpose

With regard to the Ministry's comment that "*The purpose of the regulation is to limit the health damages which the use of electronic cigarettes and refilling containers can cause for users and surroundings*", we would again highlight the growing consensus among the public health community that e-cigarettes are a) significantly less harmful than tobacco products; and b) can play a significant role in tobacco harm reduction (see footnotes 1-10). This consensus was summarised by a 2016 report by the Royal College of Physicians, which concluded that: "*Although it is not possible to quantify the long-term health risks associated with e-cigarettes*

[11] Here Fontem would point to our own manufacturing standards, which promotes responsible marketing.

precisely, 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."[12]

3.3.2 Operational scope

We agree with the Ministry that e-cigarettes with a medicinal authorisation should be exempt from consumer legislation.

However, we strongly disagree with the Ministry's inclusion of e-cigarettes in the smoking prohibition. E-cigarettes do not contain any tobacco and do not emit any smoke, and therefore should not be treated in the same way as tobacco products. Specifically regarding the Ministry's statement that medicinally licensed e-cigarettes will be included in the smoking prohibition, we would urge the Ministry to consider that this approach is a) inconsistent; and b) could undermine users' attempts to quit smoking by limiting their access to their products. In this respect, we would also question the legal and ethical legitimacy of restricting the consumption of a medicinally authorised product, particularly if it is a product which has been prescribed by a medical professional.

3.3.3 Definitions

We would highlight that the EU Tobacco Products Directive clearly exempts nicotine-free e-cigarettes from its provisions and would recommend that the Ministry follow the same approach. Robust but proportionate category-specific product quality standards should instead be developed to ensure that nicotine-free e-cigarettes are safe for use.

3.3.4 Registration requirements

Fontem Ventures would highlight the importance of ensuring that information identified by manufacturers as trade secret is robustly protected during the registration process, especially at stages where information contained in notification submissions is made publicly available. For instance, manufacturers should be permitted to list ingredients used as part of e-liquid flavours collectively as "flavourings" to maintain confidentiality.

A high level of trade secret protection is vital to the e-cigarette category: it is nascent and developing, and its success depends on manufacturers' ability to harness innovation to constantly improve and update their offering. Consequently, 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 inappropriate 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 authorities to interpret or translate what information could be disseminated into the public domain.

3.3.5 Product requirements

There are a number of statements which we would highlight in this section of the consultation memorandum.

For instance, regarding the Ministry's statement that "*Nicotine has a significantly addictive potential*", we would point the Ministry towards recent studies suggesting that nicotine consumed via tobacco-free means such as e-cigarettes has low addiction potential.[13,14]

[12] Royal College of Physicians: "Nicotine without smoke: Tobacco Harm Reduction", 28 April 2016
[13] Etter & Eisenberg: "Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes". *Drug Alcohol Depend.*, 2015.
[14] Schneider et al: "The nicotine inhaler: clinical pharmacokinetics and comparison with other nicotine treatments". *Clin Pharmacokinet.*, 2001

More generally, we would also advise that the Ministry should base any future regulatory decisions regarding nicotine on recent clinical and (if appropriate) human data, since this will provide a more accurate and up-to-date picture of its toxicological profile. For instance, although many regulators estimate the lethal dose of nicotine based on studies carried out in the 1980s[15], it has since been established that tolerance levels in fact vary widely between different individuals[16], with recent studies concluding that actual data on human exposure does not support the perceived high acute toxicity[17].

However, overall, Fontem Ventures agrees that developing robust but proportionate product requirements and standards is key to optimising product safety and to increasing consumers' confidence in the category. This will ultimately encourage more smokers to make the switch to e-cigarettes from conventional tobacco cigarettes.

First, we would highlight the fact that work is already underway to develop an e-cigarette-specific ISO standard, which we believe will be a positive step for the category. In the meantime, Fontem would recommend that robust but proportionate product standards are enacted, for instance:

- E-cigarette packaging and containers should be child- and tamper-resistant, complying as a minimum with ISO 8317 on child-resistant packaging;
- Products should as a minimum comply with basic safety requirements such as the General Product Safety Directive or ISO 9001:2008. In future, e-cigarettes should comply with specially developed international standards (e-cigarette-specific ISO certifications, for instance);
- Only ingredients of high quality should be used, for instance as a minimum all ingredients must be food grade or comply with the standards outlined in the European/United States Pharmacopeia.

At the same time, however, regulation must grant e-cigarette manufacturers the freedom to innovate and to ensure that their products remain an attractive alternative to tobacco. For instance, although no e-cigarette flavour should be designed to appeal primarily to minors, flavour variability in e-cigarettes should be permitted, since flavours have been found to play an important role in both perceived pleasure and the effort to reduce cigarette consumption or quit smoking in e-cigarette users.[18] Fontem would therefore urge regulators to consider that restricting the flavours offered to adult e-cigarette users could undermine the use of e-cigarettes as a tobacco alternative and would not lead to any clear public health benefits. Furthermore, regulators should base any decision to restrict the allowable nicotine concentration of e-liquid on up-to-date and category-specific evidence, since it is important that a range of nicotine strengths are available on the e-cigarette market so as to incentivise smokers to make the switch from tobacco products to e-cigarettes.

3.3.6 Instructions for use and labelling

Labelling of packaging: Regarding the choice of health warning, "*This product contains nicotine, which is a heavily addictive substance*", we would again point to the evidence cited in our comment above regarding section 3.3.5 that nicotine consumed via via tobacco-free means such as e-cigarettes has low addiction potential (see footnotes 13 and 14).

[15] Gosselin et al, "Clinical Toxicology of Commercial Products", 1988
[16] EFSA: "Potential risks for public health due to the presence of nicotine in wild mushrooms", *The EFSA Journal*, 2009
[17] Mayer, B., 2014: "How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century". *Arch. Toxicol.* **88:1**, 5-7
[18] K. Farsalinos et al: "Impact of flavour variability on electronic cigarette use experience". *Int. journal of env. research & pub. health*, 2013

The Ministry has proposed that e-cigarettes are labelled with a reference to quit website slutta.no. We would first ask the Ministry to reconsider if this requirement is appropriate, given that slutta.no is a smoking and snus cessation website and e-cigarettes do not contain any tobacco. Should the proposal go ahead, we would recommend that the reference should be included on the instructions for use rather than on any external packaging, so as to avoid placing another burdensome requirement on manufacturers, many of whom like Fontem already voluntarily include additional warnings such as "Not to be sold to minors" to encourage responsible sales and use of their products.

The Ministry has asked for contributions as to whether there should be nicotine warnings in place for products that do not contain nicotine but could potentially be used to consume nicotine. It is neither justifiably nor logical to require a warning against an ingredient that is not present in the product in question. Moreover, a nicotine warning on a product simultaneously labelled as "nicotine-free" could lead to significant confusion among consumers.

3.3.7 Monitoring

The Ministry should provide clear guidance to manufacturers and importers on:

- What constitutes a "less acute consequence" of e-cigarette use;
- What information they are obliged to collect; and
- What constitutes an appropriate system for collecting this information.

Moreover, the Ministry should ensure that they minimise administrative burdens for manufacturers and importers.

3.3.8 Action and warning obligations

While we agree that it is important on consumer safety grounds for the Ministry to operate a mechanism that allows them to prohibit the supply and require the recall or modification of products that are deemed to pose a serious risk to public health:

- All rulings that a product is a serious risk to public health should be supported by robust evidence from independent risk assessments specifically examining the product in question;
- Each product recall or prohibition should apply only to a specific e-cigarette or refill container model from a specific producer, rather than to a wider product "type" produced by multiple manufacturers.

3.3.9 Market monitoring on electronic cigarettes

No comments.

3.3.10 Fee and annual duty

The fees and duty proposed by the Ministry are disproportionately high and will pose a significant barrier to entry to manufacturers – an effect which is anti-competitive and risks undermining the development of the category. This is undesirable in light of the growing consensus among the public health community that e-cigarettes can play a significant role in tobacco harm reduction (see footnotes 1-10).

We would point the Ministry towards the fees set by the UK's MHRA as an example of a fee level that will best help the category to develop, boosting competition and thus benefitting consumers:
https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products#fees

3.3.11 Administrative provisions

No comments.

3.3.12 Transitional rules

No comments.