

## Submission

### Senate inquiry into measures introduced to restrict personal choice 'for the individual's own good'



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## Introduction

Fontem Ventures is dedicated to developing and growing a portfolio of innovative products including e-cigarettes. A 100% subsidiary of Imperial Tobacco Group (ITG), we nevertheless operate at arm's length from our parent company and are focusing on non-tobacco opportunities only.

Currently Fontem Ventures operates the e-cigarette brands JAI (France and Italy), and Blu (US and UK). As a responsible manufacturer, our approach is to offer quality products and to operate according to the highest levels of youth protection in our activities: we already use an age-verification mechanism to ensure that our products cannot be purchased by under-18s, for instance; and our advertising and marketing activities are governed by a strict self-imposed standard.

Fontem Ventures' submission to this Senate inquiry pertains exclusively to e-cigarettes. Unless otherwise specified, all references to e-cigarettes pertains to both nicotine-containing and nicotine-free e-cigarettes. We understand the term "e-cigarettes" to incorporate non-tobacco-based disposable or refillable devices that can be used to consume a nicotine-containing vapour via a mouthpiece, as well as their components (e.g. cartridges, tanks, or the device without a cartridge or tank).

We would like to clarify that our response does **not** pertain to the tobacco products which primarily heat rather than burn tobacco, and which certain tobacco manufacturers are trying to position as "reduced risk" products. Fontem Ventures is fundamentally opposed to any regulation, standard, code or excise category that would have the effect of linking e-cigarettes with such "heated tobacco" products. We believe regulation should strictly separate and group all products that contain tobacco, both traditional and newer tobacco products, separately from products like e-cigarettes that do not contain tobacco.

The first section of our response, "Proposed guiding principles for e-cigarette regulation", pertains to Fontem Ventures' recommendations for the principles that should guide regulators as they put e-cigarette legislation in place. The following sections provide a more detailed outline of Fontem's recommendations regarding specific areas of regulation.

## Proposed guiding principles for e-cigarette regulation

Fontem Ventures supports sound, evidence-based, reasonable and proportionate regulation of e-cigarettes that:

- **Promotes a responsible and standards-focused approach.** Manufacturers and retailers have a responsibility towards the safety of their consumers, and towards the public who may be affected by their marketing activities. Consequently, there should be tight regulations in place to ensure that products are safe for use, that manufacturers are obliged to implement child-proofing technology and packaging, that marketing demonstrates responsibility towards target and non-target audiences, and that minors may not purchase e-cigarettes or their refill containers.
- **Recognises that the clear and substantial differences between e-cigarettes and all tobacco products** means that e-cigarettes should not be subject to the same restrictions as tobacco products. As has been reiterated by many independent health organisations (including the UK anti-smoking organisation ASH<sup>1</sup>), e-cigarettes do not contain tobacco, do not emit smoke and do not involve any combustion. It is therefore unfair and inappropriate to conflate them with tobacco products.
- **Takes into account the growing consensus among health experts that e-cigarettes offer significant potential public health benefits.** Fontem believes that the potential health benefits which nicotine-containing e-cigarettes offer, coupled with the fact that there is no scientific evidence showing that e-cigarette use warrants a concern to bystanders, means that the government should be actively opening up smokers' access to high-quality and trustworthy nicotine-containing devices which provide them with an attractive alternative to tobacco products. Fontem Ventures would point the Australian Senate to the position paper published in August 2015 by the UK-based independent charity Royal Society for Public Health<sup>2</sup>, which states that:
  - *“Given that **the evidence to date so far suggests that non-tobacco nicotine containing products are safer than cigarettes**, we should ensure that we utilise these products to their full potential for smokers.”*
  - *“From a harm reduction perspective, e-cigarettes may also be a valuable tool, reducing the exposure of smokers to the many harmful carcinogens and toxicants found in cigarettes. Research conducted at University College London indicates that **for every one million UK smokers that move to e-cigarettes, 6,000 premature deaths could be avoided each year.**”*
  - *“Research to date indicates that **inhaling e-cigarette vapour is significantly less harmful to the user than smoking tobacco.**”*

We would also highlight an open letter to the WHO, which was published in 2014 and signed by over fifty health and tobacco specialists, including several Australian experts<sup>3</sup>. The letter, which categorises e-cigarettes as “tobacco harm reduction” products, states: *“**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 millions of lives.**”* It also recommends that *“**It would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products**”,* concluding that *“**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.**”*

Potential health benefits, however, are dependent on e-cigarettes remaining accessible, visible and available to the adult smokers. It is thus vital that legislators are aware of diverse unintended consequences on public health of prohibiting, limiting or “denormalizing” use of nicotine e-cigarettes which, according to the UK governmental agency Public Health England, offer the greatest potential to smokers seeking a less harmful alternative to tobacco<sup>4</sup>.

<sup>1</sup> ASH Briefing, November 2014: [E- cigarettes](#)

<sup>2</sup> August 2015, RSPH: [Stopping smoking by using other sources of nicotine](#)

<sup>3</sup> 26 May 2014, [Statement from specialists in nicotine science and public health policy](#); the signatories included Professor Ron Borland (Univ. of Melbourne; Cancer Council Victoria); Dr Coral Gartner (Univ. of Queensland); Dr Nigel Gray (WHO; Cancer Council Victoria); Professor Wayne Hall (Univ. of Queensland); Professor Richard Mattick (Univ. of New South Wales)

<sup>4</sup> McNeill et al, Public Health England, August 2015: [E-cigarettes: an evidence update](#)

## Product ingredients

### Nicotine

**Fontem Ventures would strongly recommend that the Australian authorities permit the sale and use of nicotine-containing e-cigarettes.**

The primary reason for this is that **numerous scientific studies have found nicotine containing e-cigarettes to be an effective cessation and smoking reduction aid**<sup>567</sup>. There is also emerging scientific evidence that nicotine containing e-cigarettes can also encourage reduced cigarette consumption and cessation even among those smokers not intending to quit or reject other support<sup>8</sup>. E-cigarettes have been found to be “*less addictive than tobacco cigarettes*” and “*e-cigarettes may be as or less additive than nicotine gum, which themselves are not very addictive*”<sup>9</sup>. Such findings have lead public health experts to conclude “*Electronic cigarettes consequently represent a safer alternative to cigarettes for smokers who are unable or unwilling to stop using nicotine.*”<sup>10</sup>

Moreover, numerous independent health authorities have stated that **the majority of smoking-related diseases are caused not by nicotine but by the generation of harmful or potentially harmful smoke constituents (HPHCs) from the burning of tobacco**. Unlike tobacco products, e-cigarettes do not contain tobacco, do not burn, and do not smoulder unlike tobacco products. ASH UK, for instance, states: “*Nicotine is the addictive element of tobacco but it is the tar and other toxins in tobacco smoke, not nicotine, that cause most of the harm.*” They add that “*Electronic cigarettes consequently represent a safer alternative to cigarettes for smokers who are unable or unwilling to stop using nicotine.*” This stance is reiterated by NICE (the UK public body National Institute for Health and Care), who state that “*it is primarily the toxins and carcinogens in tobacco smoke - not the nicotine - that cause illness and death*”<sup>11</sup>.

However, **Fontem would advise the Australian government to limit nicotine to levels that, while allowing consumers a satisfying experience**, ensure that consumers do not risk overexposure to nicotine during normal use of their products. Fontem Ventures would point Australian regulators to the nicotine concentration limits stipulated by the EU Tobacco Products Directive<sup>12</sup>, which stipulates the following:

- Nicotine-containing liquid may only be placed on the market in dedicated refill containers not exceeding a volume of 10ml or in cartridges or tanks not exceeding a volume of 2ml
- Nicotine-containing liquid may not contain nicotine in excess of 20mg/ml

### Flavourings

**We would strongly recommend that flavourings and variability are permitted in e-liquids**. Not only are flavourings important for perceived pleasure during e-cigarette use, but recent studies have suggested that e-cigarette flavours play a major role in reducing relapse into tobacco smoking<sup>13</sup>.

Indeed, a flavouring component is essential in making e-cigarettes usable; its absence would severely diminish the products’ usability and acceptance in the market. This is a highly undesirable outcome in light of the growing medical consensus that e-cigarettes offer huge potential health benefits.

A blanket ban on flavourings could also result in consumers taking matters into their own hands to make “unflavoured” products more palatable, either by purchasing flavoured e-liquids illegally, or customising their e-liquids with domestically available flavourings or extracts (e.g. food or alcoholic products, food flavourings, extracts, or even perfumes). Since these home-mixed e-liquids will be not have been

<sup>5</sup> McNeill et al, Public Health England, August 2015: [E-cigarettes: an evidence update](#)

<sup>6</sup> Rahmann et al, March 2015: [E-Cigarettes and Smoking Cessation: Evidence from a Systematic Review and Meta-Analysis](#)

<sup>7</sup> Polosa et al, October 2011: [Effect of an electronic nicotine delivery device on smoking reduction and cessation](#)

<sup>8</sup> Polosa et al, November 2014: [Success rates with nicotine personal vaporizers](#)

<sup>9</sup> Etter & Eissenberg, February 2015: [Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes](#)

<sup>10</sup> ASH Briefing, November 2014: [E- cigarettes](#)

<sup>11</sup> June 2013: NICE Guidance - [Smoking tobacco harm reduction approaches](#)

<sup>12</sup> [Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC](#)

<sup>13</sup> Farsalinos et al, 2013: [Impact of Flavour Variability on E- Cigarette Use Experience: An Internet Survey](#)

subjected to any professional laboratory testing or toxicity analysis, they could pose significant oral, respiratory and dermal risks to consumers.

**We do agree, however, that some restrictions should be in place to ensure that flavours do not particularly appeal to young people.** Fontem Ventures is of the view that flavours that clearly appeal primarily to minors (e.g. candy flavours, bubblegum, milkshake) should not be marketed. Please note, however, that this is a precautionary approach and should be implemented with care; as the Public Health England 2015 report notes, uptake of e-cigarettes by under-18s is minimal, and restrictions to flavours used by adult e-cigarette users could have a negative impact on this adult group while providing no public health benefits to minors<sup>14</sup>. A generally wide variety of flavourings should be permitted, combined with a ban on clearly youth-targeted flavourings, as well as a strict prohibition on e-cigarette sales to minors (see “Sales restrictions”). Indeed, the latter measure is likely to be a more effective deterrent to the (already very few) users in this age group.

### **Other ingredients**

As a responsible manufacturer, we would thoroughly support a ban on e-liquids containing substances and additives which are proven to be harmful to human health. It is important, however, that e-liquid manufacturers are permitted to use toxicologically approved natural extracts or oils which are safe for use, as these substances can help improve flavour, making the products more palatable to consumers and potentially encouraging more smokers to switch to using e-cigarettes.

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<sup>14</sup> McNeill et al, Public Health England, August 2015: [E-cigarettes: an evidence update](#)

## Product safety & standards

Standards bodies in several countries have begun publishing guidelines for manufacturers. Fontem Ventures would point the Australian government towards those issued by the French standards body AFNOR<sup>15</sup>, which we believe constitute a thorough set of guidelines that will help ensure consumer safety whilst driving up industry standards and building confidence in the e-cigarette category.

Since it can take some time to draw up such detailed guidelines, however, **Fontem Ventures would advise in the meantime that the Australian government put some minimum standards in place to ensure consumer safety.**

### E-liquids

As part of these minimum standards, **Fontem would recommend stipulating that only ingredients of high purity may be used in e-liquids, and that no ingredients that are known carcinogens, mutagens or reprotoxins may be used.** Fontem would also recommend including the requirement that **only ingredients are used in the nicotine-containing liquid that are toxicologically suitable in heated or unheated form.** To ensure consistency across the board, our recommendation would be that **nicotine, propylene glycol and glycerol must comply with appropriate pharmacopeia standards and flavourings must be food grade.**

### Devices

**Regulations should stipulate that devices and e-liquid containers must be child- and tamper-proof, and are protected against breakage and leakage.** Since the safety of electronic cigarettes and refill containers and their propensity for leakage can vary according to product type, the Australian government should seek advice from the industry and closely consider different types of devices and refill containers as they draw up requirements for product technology.

We would also advise the Australian government to include the requirement that **e-cigarettes deliver the nicotine doses at consistent levels under normal conditions of use, i.e. as recommended by the manufacturer.**

### Product labelling and packaging

**Manufacturers should be obliged to print important information on the unit packets and any outside packaging of e-cigarettes and refill containers.** This should include:

- A list of ingredients
- A clearly visible warning that the product contains nicotine and should be kept out of reach of children
- A recommendation that the product is not for use by non-smokers
- A warning stating “Not for sale to under-18s”

**All unit packets should include a leaflet with information on instructions for use and storage** (including a reiteration that the product is not recommended for use by young people and non-smokers), as well as health-related information including warnings for specific risk groups, possible adverse effects, and contact details of the manufacturer or importer. In addition, external packaging should be child- and tamper-proof.

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<sup>15</sup> A summary of the AFNOR guidelines can be viewed in their [press release dated 7 April 2015](#); the full standards can be purchased in two parts, [XP D90-300-1 Mars 2015](#) and [XP D90-300-2 Mars 2015](#)

## Sales restrictions

### Therapeutic goods

The Australian government **should permit the sale of nicotine-containing e-cigarettes which have not been approved as therapeutic goods, provided that they comply with appropriately stringent product and safety standards, particularly with regard to limits on their nicotine content and concentration** (see “Product ingredients”). Although several e-cigarette manufacturers, including Fontem Ventures, are already working on marketing medically authorised e-cigarettes, the process will naturally take some time. In the meantime, from a health perspective it seems counter-productive to block access to a product which offers consumers an attractive and tobacco-free alternative to smoking. According to the UK anti-smoking charity ASH, *“Electronic cigarettes are proving more attractive to smokers than NRT while providing them with a safer alternative to cigarettes. There is evidence that they can be effective in helping smokers’ quit and little evidence that they are being used by never smokers.”*<sup>16</sup>

### Age limits

**EVPs should only be marketed and sold to adults:** they are intended for and should only be used by an adult consumer group. Subsequently, **Fontem Ventures supports regulation that prevents inappropriate age groups from accessing the products**, for instance legislation which restricts the access and consumption of nicotine products by anyone under the age of 18, and laws making it an offence to proxy purchase nicotine-containing products for minors. In this context, Fontem has developed a number of youth protection initiatives, including a marketing code of conduct (see “Marketing and advertising”).

### Sales channels

In light of the growing consensus among health professionals regarding e-cigarettes’ potential public health benefits, **Fontem Ventures would recommend that the widest possible range of sales channels be left open for e-cigarettes to encourage maximum uptake by smokers.** However, we would also recommend that regulation **requires manufacturers to put adequate protections and mechanisms to ensure that products: a) comply with Australian product safety standards; and b) are not available for purchase by minors.**

For instance, **distance sales (e.g. internet sales) should be permitted. However, such channels should be subject to strict regulations:** for example, as per the legislation which is shortly to enter into force across the EU, retailers selling e-cigarettes via distance channels must operate age-verification systems to prevent e-cigarettes from being sold to under-18s. In addition, implementing a registration and verification scheme would ensure that all products comply with Australia’s standards and requirements.

Fontem would also recommend that **vending machines be permitted, provided that they cannot be used by minors.** This can be achieved by limiting their availability to over-18 establishments or machines with an age verification, or by limiting access to vending machines through interaction with staff.

Fontem would also advise that **e-cigarettes are available for purchase in all outlets where tobacco products are sold**, so as to establish them more firmly as a tobacco alternative.

### Public display

**Fontem would advise that e-cigarettes or nicotine-containing liquids are permitted to be displayed at retail sales points.** This will help to raise awareness and visibility of e-cigarettes as an alternative to tobacco, and will enable retailers to provide consumers with vital product information.

### Vendors

**Fontem Ventures would support the creation of a register of e-cigarette and e-liquid vendors** - this would help drive standards up across the industry. It is important, however, that e-cigarettes have a separate register from tobacco products as e-cigarettes do not contain tobacco.

<sup>16</sup> ASH Briefing, November 2014: [E- cigarettes](#)



## Marketing & advertising

We would recommend that **the scope and content of e-cigarette advertising and promotion be regulated so as to minimise targeting of and impact on under-18s and non-smokers**. We would point the Australian government towards the UK's current system of regulating the advertising of e-cigarettes; it is exemplary in that while it takes into account the potential health benefits of e-cigarettes, it also minimises advertisements' appeal to young people and non-smokers<sup>17</sup>. Fontem Ventures also operates according to a strict self-imposed marketing standard, with similar restrictions on the content which is considered appropriate<sup>18</sup>. Notable stipulations include:

- Marketing should not imply any performance or functional benefits that are not supported by reliable evidence
- Marketing will only be aimed at adults
- Marketing will not use images, symbols, tropes, games etc. that appeal primarily to minors

We would recommend that nationwide regulations are nuanced, and take a strong youth-protection-driven approach.

However, **we would caution against excessively restricting the range of formats permitted for advertising or promoting e-cigarettes**, for instance via bans on billboards or on advertising banners at point of sale. It is vital that e-cigarette retailers and manufacturers are able to raise awareness of what is still a very new category via advertising: not only does this enable them to disseminate information to the public, but it ensures that e-cigarettes become widely known as an alternative to tobacco products. Importantly, it also enables the products to compete on a level playing field with tobacco products and other tobacco alternatives, such as nicotine replacement therapies (NRT).

Fontem Ventures' position is reflected by the open letter to the WHO published in May 2014 (cited in our "proposed guiding principles"), which states explicitly:

*"It is counterproductive to ban the advertising of e-cigarettes and other low risk alternatives to smoking. The case for banning tobacco advertising rests on the great harm that smoking causes, but no such argument applies to e-cigarettes, for example, which are far more likely to reduce harm by reducing smoking. Controls on advertising to non-smokers, and particularly to young people are certainly justified, but a total ban would have many negative effects, including protection of the cigarette market and implicit support for tobacco companies. It is possible to target advertising at existing smokers where the benefits are potentially huge and the risks minimal. It is inappropriate to apply Article 13 of the FCTC (Tobacco advertising, promotion and sponsorship) to these products."*

Fontem Ventures agrees entirely with this statement, and believes it offers a balanced view of e-cigarette advertising while offering proper protection to children, adults and non-smokers.

<sup>17</sup> Published October 2014: "[New rules for the marketing of e-cigarettes](#)"

<sup>18</sup> Fontem Ventures [Marketing Standard](#)

## Use of e-cigarettes in public places

Fontem Ventures would strongly recommend that the Australian government permit the use of e-cigarettes in the majority of public places, other than places which are primarily child-oriented (e.g. schools). We take this view because the accessibility of e-cigarettes is a significant factor in encouraging consumers to make the switch from tobacco products. Making e-cigarettes an appealing alternative to tobacco is a desirable outcome in light of the growing consensus among health experts that such a switch offers significant potential health benefits.

Indeed, there is strong support among the international medical community for a regulatory regime that maintains their accessibility. See, for instance, the open letter to the WHO published in May 2014 (mentioned in the introduction to this questionnaire), which states that:

*“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. Decisions on whether it is permitted or banned in a particular space should rest with the owners or operators of public spaces, who can take a wide range of factors into account. Article 8 of the FCTC (Protection from exposure to tobacco smoke) should not be applied to these products at this time.”*

Fontem Ventures would strongly advise against implementing a tobacco-style blanket ban on using e-cigarettes in public places:

- **Such a ban could undermine the potential health benefits of e-cigarettes**, as it will reduce their appeal to tobacco smokers. In addition, forcing e-cigarette users (the vast majority of whom are former or current smokers trying to reduce or stop their tobacco consumption<sup>19</sup>) to share a space with smokers may jeopardize their attempts to quit, in addition to exposing them to tobacco smoke.
- **There is no scientific evidence to date to suggest that e-cigarette use has any harmful impact on bystanders.** 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 vapour exhaled by the consumer into the air but not to smoke. Numerous reviews of the scientific literature have concluded that exposure to nicotine and other chemicals that may be present in exhaled e-cigarette vapour is negligible with all chemical analyses to date indicating exhaled e-cigarettes vapour does not warrant a health concern to bystanders<sup>20 21 22 23</sup>. Meanwhile, Fontem Ventures has published its own peer-reviewed research showing that vaping indoors does not release chemicals in levels that would endanger bystanders or users when compared to the regulatory standards that are used for workplaces or general indoor air quality<sup>24</sup>. Ambient air in a room in which three people had used Fontem’s e-cigarettes for almost three hours still complied easily with workplace exposure limits for all chemicals analysed.
- **The overwhelming majority of scientific evidence also show e-cigarettes are not “renormalizing” the act of smoking or serving as a “gateway” to tobacco products**, particularly amongst youngsters. 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*”

<sup>19</sup> ASH, May 2015: [“Use of e-cigarettes \(vapourisers\) among adults in Great Britain”](#)

<sup>20</sup> McNeill et al, October 2014: [“A critique of a WHO-commissioned report and associated article on electronic cigarettes”](#)

<sup>21</sup> McNeill et al, Public Health England, August 2015: [E-cigarettes: an evidence update](#)

<sup>22</sup> Burstyn, January 2014: [Peering through the mist: Systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks](#)

<sup>23</sup> Saitta et al, March 2014: [Achieving appropriate regulations for electronic cigarettes](#)

<sup>24</sup> O’Connell et al, May 2015: [An Assessment of Indoor Air Quality before, during and after Unrestricted Use of E-Cigarettes in a Small Room](#)

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## Contact details

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