



# **Responsible Practice in E-Vapour Products (EVP) Product Stewardship**

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#### **Responsible Practice**





#### Responsible practice can be divided in to 3 areas:



#### **Pre-market product stewardship**





# **Responsible Practice**



Todays' presentation



Focus today on batch release and post-market product stewardship

- Emphasis on testing approaches and strategies

## **Batch Release**

#### Manufacturing Quality – Process Control





Source: BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly related products – Manufacture, importation, testing and labelling - Guide

### **Batch release**

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Traceability









Why is it important?



"In a nutshell, best estimates show ecigarettes are 95% less harmful to your health than normal cigarettes



All of the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long term effects.



"ENDS use poses serious threats to adolescents and foetuses"

# **Regulatory Frameworks**

What is pre-market & what is post-market?





The '4 Big' Questions







Q1 Impact of EVP on Consumers

Clinical Studies Registered	Clinical Studies published since 2011	Outcomes investigated in these studies
>100 studies registered on ClinicalTrials.gov	>30 scientific publications for Randomised Clinical Trials identified	<ul> <li>Safety and Tolerability</li> <li>Nicotine PK</li> <li>Smoking reduction</li> <li>Subjective effects</li> <li>EVP vs Nicotine Inhalator</li> <li>EVP awareness, use and harm perceptions</li> <li>Cardiovascular function</li> <li>Evaluation of weight gain</li> <li>Use amongst smokers with mental illness</li> <li>Consumer behaviour &amp; Topography</li> <li>Biomarkers of Exposure &amp; Biomarkers of Biological Effect</li> </ul>
Huge investment and research invested in clinical studies	>10 scientific publications for Non- Randomised Clinical Trials identified	

Q1 Impact of EVP on Consumers

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#### Registry

- "Real world" data
- Large "N"
- Observational
- Hypothesis generating
- Effectiveness
- Flexible, sub-studies
- Opportunistic or mandatory

#### **Clinical Trial**

- Formatted data (selection criteria)
- Small "N"
- Usually randomized
- Hypothesis driven
- Efficacy
- Powered
- Usually mandatory



Q1 Impact of EVP on Consumers



Increased duration of use; 'artificial' to 'real life-settings'



Q2 Impact of EVP on bystanders



Exhaled breath analysis shows far fewer peaks compared to conventional cigarette

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#### Q2 Impact of EVP on bystanders

Detected at low levels at all sampling times and substantially below respective WHO or Indoor Air Quality Guideline levels



#### Acrolein

Source: O'Connell *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**, 12, 4889-4907.



Q2 Impact of EVP on bystanders

Closed system e-cigarette



Open system e-cigarette

No difference in the levels of nicotine detected on the surfaces before, during or after use of both the closed and open system e-cigarettes

Source: O'Connell *et al.* An assessment of nicotine levels on office surfaces before, during and after use of electronic cigarettes. *In preparation* for poster presentation at Society for Research on Nicotine and Tobacco (SRNT), Italy, 2017

Q3 Does EVP act as a gateway to tobacco

Two behavioural studies conducted by the UK Centre for Substance Use Research (funded by Fontem Ventures)



- Investigating EVPs and smoking initiation, relapse and dependency on nicotine
- 24,000 vapers enrolled



- EVPs are a roadblock to smoking initiation not a gateway
- EVPs de-normalise smoking, rather than renormalise it



Q3 Does EVP act as a gateway to tobacco

**Dynamic Population Modelling** 

Probability that never-user will come to smoking via EVPs whereas if EVPs does not exist they would still never-smoker



Gateway effect P3 + P4 - (P1 - P2)

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Q4 Addictiveness & Health Impact of Nicotine

Nicotine is regarded as addictive	<ul> <li>Nicotine is regarded as addictive</li> <li>EVPs meet consumers smoking-ritual needs</li> <li>Growing evidence that EVPs support smoking cessation</li> </ul>
No toxicity concern	<ul> <li>No toxicity concern with nicotine in the small doses in an EVP</li> </ul>
Long term health risks?	<ul> <li>USSG: Science is inadequate to conclude either way on nicotine and cancer</li> <li>Any long term risks are unknown</li> <li>Further long term research is required</li> </ul>



Answers to the '4 Big' Questions



Consumer perception and behaviour assessment

Post-market surveillance

#### **Summary** Responsible Practice in EVP Product Stewardship





# Thank you for your attention!





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