Next Generation Products
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• Science and standards

• Substantiating the risk reduction potential of next generation products
Consumer landscape

• WHO current global estimates 1.4 Bn adult smokers

• E-cigarette use growing annually

• Smokeless tobacco widely used in Nordics and US

• Tobacco Heating Products are coming back on radar
BAT’s risk spectrum

- CONVENTIONAL CIGARETTES
- TOBACCO-HEATING PRODUCTS
- LOW-TOXICANT SMOKELESS TOBACCO
- ELECTRONIC CIGARETTES
- LICENSED MEDICINAL PRODUCTS

Exposure to toxicants:
HIGH → LOW
Tobacco Heating Products: The journey

Premier & Eclipse are products of the RJ Reynolds company; Accord, Heatbar and iQOS are products of the Philip Morris (International) company; Ploom and Ploom Pax are products of the Japan Tobacco International company.
Snus...the Swedish experience

Tobacco usage in Sweden¹

SNUS demonstrating potential for harm reduction²

²International agency for research on cancer
E-cigarettes: evolution of a consumer driven category

- **Time**
  - 1st gen
  - 2nd gen
  - 3rd gen
  - 4th gen

- **Devices**
  - 1st gen: Cigarette
  - 2nd gen: Dual cigarettes
  - 3rd gen: Electronic cigarette
  - 4th gen: Electronic cigarette

- **E-liquids**
  - Tobacco
  - Menthol
  - Fruits
  - Beverage
  - Other

- **Customisation**
  - Bluetooth
  - RFID
  - Charging packs
  - Power control
  - Puff counter

- **Mixology**
E-cigarettes: Motivations for vaping*

Global survey of EC users

- 7,326 Vapers surveyed
- Languages: English, French, Italian, Spanish, Russian, Polish, German (June 1st – Aug 30th 2015)
- 4,235/5000 (85%) smokers quit
- 56% of 754 dual-users reduced CPD by >50%

*Research Funded by Nicoventures, the Next Generation Products business of the British American Tobacco group of companies
Number of Vapers increasing….. should there be more?

"There has been an overall shift towards the inaccurate perception of EC being as harmful as cigarettes over the last year in contrast to the current expert estimate that using EC is around 95% safer than smoking."

While perception is growing that e-cigs are less harmful than cigs, the consumer remains poorly informed.

E-cigs have seen exponential growth but the consumer needs better information through an aligned coalition of science.

*Action on Smoking on health, UK
Product standards that protect the consumer and enable business growth

- Liquid purity
- Charging safety
- Aerosol chemistry
- Component verification
- Marketing freedoms
- Differentiation
- Innovation
- Fiscal policy

Aligned with BSI, Afnor etc.
Safety science via Product Stewardship

Stewardship Science

3) In vitro toxicology

2) Chemical and physical characterisation

1) Product stability

PUBLICATIONS AND MEDIA

• EpiAirway aerosol methodology in *Toxicology In Vitro* 2015
• Press release – 52,000 downloads
• Bat-science news story viewed >1000 times
• Twitter reaction – story has reached hundreds of thousands of vapers
Science to substantiate risk reduction

**TYPE OF STUDY**
- Post-market surveillance
- Consumer perception study
- Systems Science
- Biomarker of effect study
- In vitro models of disease
- Exposure and pharmacokinetic studies
- Computational toxicology
- In vitro regulatory toxicology
- Chemical and physical characterisation
- Product design stability

**PURPOSE**
- Population risk reduction
- Individual risk reduction
- Toxicant exposure reduction
- Stewardship science
Reduced exposure to toxicants: THPs and E-cigarettes*

*Tests performed on a BAT products (prototype Tobacco Heating Product and a commercial e-cigarette)
**In Vitro Models**

*In Vivo* (performed in the living) to *In Vitro* (performed in the laboratory)

- Tissue biopsy (cells are undisrupted)
- One cell type isolated in culture

Different product aerosols

Different biological exposure methods

- Air-Liquid Interface
- Submerged (AqE)
- Submerged (PM)
Chemistry reductions driving reduced responses \textit{in vitro}

- No observed mutagenicity for prototype tobacco heating product or e-cigarette under these test conditions.
- Significant reductions in cytotoxicity for THP and E-cigarette versus reference cigarette under these test conditions.
Promising preliminary results...

**Oxidative stress**

- Reference Cigarette 3R4F
- Prototype tobacco heating product
- E-cigarette

% Vehicle control vs. AqE (%)

**DNA damage**

- Reference cigarette 3R4F
- Prototype tobacco heating product
- E-cigarette

Average intensity vs. Mass (µg/cm²)

**Cell transformation**

- Reference cigarette 3R4F
- Prototype tobacco heating product
- E-cigarette

Mean foci number vs. TPM Concentration (µg/mL)

**THP and e-cigarettes showed**:

- greatly reduced reductions in oxidative stress versus reference cigarette
- no genotoxic responses under these test conditions
- significant reduction in tumor promotion observed with e-cigarette and THP versus reference cigarette under these test conditions
Risk reduction potential of next generation products*

Harm reduction = Reduced risk x Number who switch

• Dependent on a substantiated reduction in toxicity of the product through a range of integrated studies

• Dependent on the number of people who switch from cigarettes

*Clive Bates (former director of Action on Smoking & Health, UK), E-cig summit, 2013
Take home messages

• Evolution of consumer relevant, potentially reduced risk tobacco and nicotine products

• Preliminary data shows that these products have the potential to reduce risk versus cigarettes

• Series of integrated studies over time required to substantiate reduced risk

• Common product standards and agreed testing platforms required