TO BUILD TRUST A PRODUCT MUST FIRST HAVE AN ACCEPTABLE SAFETY PROFILE, AND REDUCE RISKS RELATIVE TO SMOKING

What’s the safety profile of the product? (Absolute risk)

Is it substantially reduced risk relative to combustible cigarettes? (Relative risk)

What are the risks and benefits to the population as a whole?

“e-cigarettes are 95% safer than tobacco, but fewer than half of smokers are aware of this fact”

“Whilst investigations are ongoing we recommend that you consider refraining from using e-cigarette, or vaping, products, particularly those containing THC”
PRODUCT SAFETY & STANDARDS IS THE FIRST PRIORITY

Safety Assessment

**Product Standards**
- Quality of ingredients, materials, and component parts
- Full product characterisation
- Standardised product safety tests
- Standardised laboratory methods
- Robust risk assessment of final product by qualified professionals

**Quality Control**
- In design
- In manufacture
- Batch release
- Product testing
- Microbiological testing
- Stability testing

**Regulatory Compliance**
- General Safety regulations
- Tobacco Product regulations
- Device specific regulations
- Packaging & Labelling regulations

**Mitigating Product Safety Risks**
- What’s the absolute risk profile of the product?
- Modification required?
- Warning required?
- Other mitigating actions? (e.g. responsible marketing)
ROBUSTLY TESTED PRODUCTS MUST BE DEMONSTRATED TO BE REDUCED RISK RELATIVE TO COMBUSTIBLE CIGARETTES.
THE POTENTIAL BENEFITS TO THE POPULATION ARE SUBSTANTIAL

2009\textsuperscript{a} 2017\textsuperscript{b} 2018\textsuperscript{c}

29% 26% 17%

28% 14.4% 

\textsuperscript{a} Special Eurobarometer 332 (2009)
\textsuperscript{b} Special Eurobarometer 458 (2017)
\textsuperscript{c} UK Office for National Statistics (2019)
ASSESSING THE RISKS & BENEFITS MUST INCLUDE THE PRODUCTS POTENTIAL, WHETHER IT WILL BE USED BY ADULT SMOKERS, AND ANY UNINTENDED CONSEQUENCES

Population Harm Reduction = Reduced Risk Potential x Consumer Acceptance

Consumer Acceptance = Product Appeal to current adult smokers + Sustained Product Use by current adult smokers - Unintended Use by youth and never smokers
THE SIMPLIFIED HARM REDUCTION EQUATION

Population Harm Reduction = Reduced Risk Potential

Product Appeal + Sustained Product Use - Unintended Use

Product Appeal to current adult smokers

Sustained Product Use by current adult smokers

Unintended Use by youth and never smokers

“off-ramping” from smoking

“on-ramping” onto nicotine
REDUCED RISK POTENTIAL MUST BE CONTINUALLY ASSESSED THROUGH ROBUST FRAMEWORKS

- Product Characterisation
- Biological Science
- Data Analytics
- Clinical Science
- Perception & Behavioural Science
- Population Health Science

Imperial Brands Science
IS THE PRODUCT WELL DESIGNED AND MANUFACTURED, AND DOES IT SUBSTANTIALLY REDUCE EXPOSURE TO HPHCS*

Product Design & contents
Product Use & Dosimetry
Manufacturing Controls
Product & Device safety cf. other consumer products
HPHCs compared to cigs
Particle size of any aerosol
Stability testing
Extractable & Leachables
Untargeted screening

*Hazardous and Potentially Hazardous Constituents
DOES PRE-CLINICAL DATA SHOW THAT THE PRODUCT IS POTENTIALLY REDUCED RISK AND IS APPROPRIATE FOR CLINICAL STUDIES?
DOES YOUR CLINICAL DATA SUBSTANTIATE REDUCED RISK POTENTIAL AND DEMONSTRATE IT’S RELATIVE SAFETY AND EFFICACY

Pharmacokinetics of nicotine delivery
Pharmacodynamics of nicotine delivery
Reduction in biomarker or exposure
Reduction in biomarkers of harm

Lung function & health
Cardiovascular effects
Safety & Tolerability (inc. Adverse Events)
Combustible cigarette use
IS THE IMPACT ON THE ENVIRONMENT ACCEPTABLE?

Indoor Air Quality
Exposure to by-standers
Land Use
Emissions to air and water feeds
Waste disposal from manufacturing
Recycling Schemes
Landfill
DO YOU UNDERSTAND HOW THE PRODUCT IS USED?

Risk Perception

Use Behaviour

Intentions to Use

Comprehension & Labelling

Cross Sectional & Cohort

Product Misuses

Safety Tracking

Population Models
DO YOU HAVE THE SYSTEMS IN PLACE TO CONTINUALLY ASSESS THE SAFETY OF THE PRODUCT, AND RESPOND?

- Evaluate scientific & medical literature
- Assess consumer health complaints
- Monitor notifications to regulators
- Studies to assess benefit/impact on population
SUMMARY

1. Robust product safety assessment first
2. Regulators must set product standards
3. Comprehensive programmes are required to assess reduced risk potential
4. Reduced risk potential is a continual assessment
5. Population benefits and risks is a holistic assessment