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Studies support reduced risk potential of the Vype ePen e-cigarette

- A science-based testing programme has been developed by scientists at British American Tobacco to assess the potential health risks of e-cigarettes and other innovative smoking alternatives, compared to conventional cigarettes
- Tests on Vype ePen, a commercially available e-cigarette, reveal the relatively simple nature of Vype ePen vapour compared to cigarette smoke, that it has little or no impact on human cells in certain lab-based tests and that it effectively delivers nicotine to the user
- The results of one test don't mean much on their own, but the combined results of all these tests build a picture of a product with the potential to be substantially reduced-risk compared to cigarettes.

25 September 2017, Southampton, UK: Scientists at British American Tobacco (BAT) have created the most comprehensive database of scientific test results, to date, for an e-cigarette (Vype ePen). The results of the studies provide evidence that suggests Vype ePen has the potential to be substantially reduced risk compared to traditional cigarettes.

This database was created using data collected from a series of scientific tests that could form the basis of a template to support health-related claims such as 'reduced risk' compared to conventional cigarettes for e-cigarettes, as well as for other innovative next generation products, like tobacco heating devices.

"This is a very new consumer category and both consumers and regulators rightly want as much information as possible about the products available," said Dr David O'Reilly, Group Scientific and R&D Director at British American Tobacco.

"We believe a science-based approach is vital to gathering the evidence needed to demonstrate the reduced-risk potential of e-cigarettes and other products, which is why testing products like Vype ePen in this way is so important. We intend for this to be the first of many applications of our scientific assessment framework," he said.

The application of BAT's approach to the scientific assessment of potentially reduced-risk products is reported today in the journal *Regulatory Toxicology and Pharmacology*, where the results of 17 published studies on Vype ePen are described.

The tests used include:

Preclinical studies, which demonstrate the relatively simple composition of the Vype ePen vapour compared to conventional cigarette smoke (Figure 1) – there are around 95% less toxicants in Vype ePen vapour.*

* Comparison of smoke from a 3R4F reference cigarette (approx. 9 mg tar) and vapour from Vype ePen, in terms of the 9 harmful components the World Health Organisation recommends to reduce in cigarette smoke. These results do not necessarily mean that this product produces less adverse health effects than tobacco products.]



Further tests revealed that this vapour has a much-reduced or no biological impact on human cells in the laboratory, compared to conventional cigarette smoke, depending on the test used (Figure 2).

Clinical Studies, which involve humans, revealed that Vype ePen vapour delivers nicotine to the consumer as efficiently as cigarette smoke – this is an indicator of whether the product may provide smokers with a satisfactory alternative to a cigarette.

Population studies, which use predictive modelling to estimate an overall harm reduction effect of the product on a population. BAT's studies indicate that the wide availability of an e-cigarette such as Vype ePen, can have an overall harm reduction effect because more people may quit smoking when e-cigarettes are widely available.

Taken together, these results form the basis of a comprehensive dossier of scientific data that lay the groundwork for establishing this product's reduced-risk potential compared to cigarettes*.

This dossier of results presents the kind of information that regulators like the US Food and Drug Administration want when any company submits a Modified Risk Tobacco Product application in order to introduce novel reduced-risk tobacco products to the US market.

It can take years to create such a dossier and our scientists say that it would be impractical to create a new dossier every time a product is tweaked.

“This category is so fast moving that there are new and improved products appearing all the time. If for example, a scientific dossier was required before these products could go on the market, this could drastically impact the availability of new and improved products and their value in tobacco harm reduction,” said Dr James Murphy, Head of Reduced Risk Substantiation at British American Tobacco.

“Importantly, this sort of framework could provide datasets for product families so that full scientific tests wouldn't need to be done with every new generation of the same product – making the innovation process faster whilst still giving consumers and regulators assurances around the relative risk of each product. This could mean improved products with harm reduction potential can be developed, assessed and brought to market more quickly without duplicating tests. We are urging regulators and public health officials to look at this methodology in this context.” Murphy concluded.

ENDS

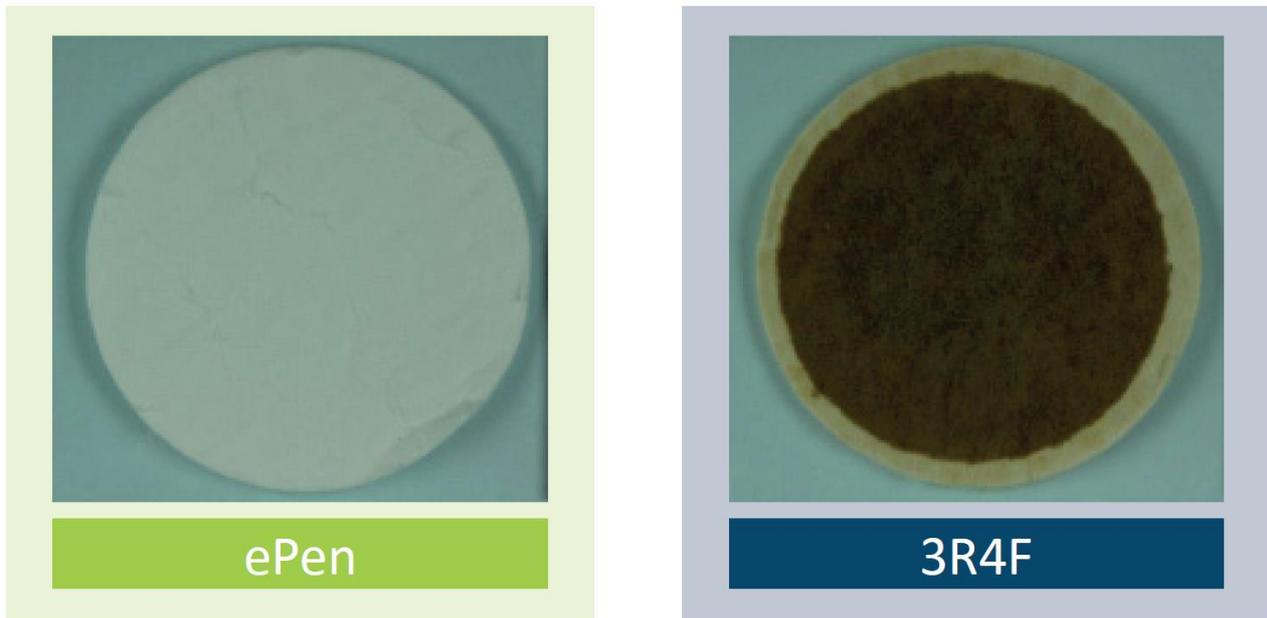


Figure 1. Filter pads with e-cigarette aerosol (left) and smoke from reference cigarettes (right).

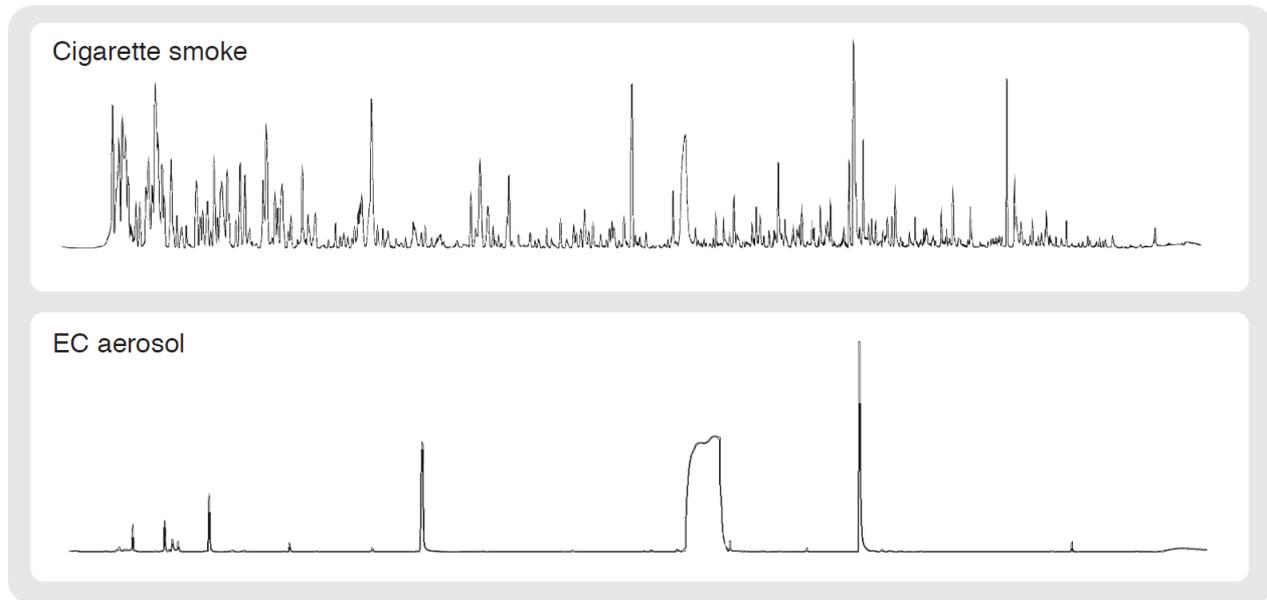


Figure 2. Chromatographic analysis of cigarette smoke and e-cigarette aerosol.



NOTES TO EDITORS

About British American Tobacco: British American Tobacco is a global tobacco and next generation product company with brands sold in more than 200 markets. It employs more than 50,000 people worldwide and has over 200 brands in its portfolio, with its cigarettes chosen by one in eight of the world's one billion smokers. Leading global brands include Dunhill, Kent, Pall Mall and Lucky Strike.

About Next Generation Products (NGP): Next Generation Products is part of the British American Tobacco Group and is focused on developing and delivering high-quality alternative nicotine and tobacco products for adult smokers in the key areas of Vapour and Tobacco Heating Products. For more information see www.goVype.com and www.bat-science.com.

About Tobacco Harm Reduction: The only way to avoid the risks associated with tobacco use is not to consume tobacco at all, and the best way to reduce the risks is to stop using tobacco. However, the concept of harm reduction is increasingly being considered in relation to tobacco use. Harm reduction is about finding practical ways to minimise the health impact of an inherently risky activity or behaviour, without seeking to stop it entirely. It is a key element of BAT's business strategy and is being discussed by some regulators. We think it's important to work towards producing consumer-acceptable, potentially reduced risk products. We believe that tobacco regulatory policies should include harm reduction approaches for the millions of adults globally who will continue to consume tobacco products.

The Public Health Impact of e-cigarettes and other Next-Generation Products: Many in the public health community believe e-cigarettes offer great potential for reducing the public health impact of smoking. Public Health England, an executive body of the UK Department of Health, recently published a report saying that the current expert estimate is that using e-cigarettes is around 95% safer than smoking cigarettes. The Royal College of Physicians have said that the public can be reassured that e-cigarettes are much safer than smoking and that they should be widely promoted as an alternative to cigarettes.

