

Innovative Choices



2018 Harm Reduction Focus Report

Our Group strategy and sustainability agenda

Our Group vision is to be the world's best at satisfying consumer moments in tobacco and beyond. Our strategy focuses on the four key areas of growth, productivity, winning organisation and sustainability.

As a key strategic focus area, sustainability is crucial to the delivery of our Group strategy and is integrated across all areas of our business. In particular, three key areas have been identified through a detailed materiality process as having the greatest significance to our business and our stakeholders:

Harm Reduction

We are committed to working to reduce the public health impact of smoking, through offering adult consumers a range of potentially reduced-risk products (PRRPs).

Sustainable Agriculture and Farmer Livelihoods

We are committed to working to enable prosperous livelihoods for all farmers who supply our tobacco leaf.

Corporate Behaviour

We are committed to operating to the highest standards of corporate conduct and transparency.

Performance across all three areas can be found in our annual <u>Sustainability Report</u>.

In addition, we produce in-depth Focus Reports on each area of our sustainability agenda. This Focus Report addresses specifically the area of harm reduction.

What is harm reduction?

Harm reduction is a well-established public health concept that seeks pragmatic ways to minimise the impact of an inherently risky activity without stopping it entirely.

Our approach to tobacco harm reduction focuses on enabling adult smokers who want to continue consuming tobacco or nicotine to use products known as potentially reduced-risk products (PRRPs). We use the term PRRPs to cover tobacco and nicotine products that, based on the available science, have been shown to be reduced-risk; are likely to be reduced-risk; or have the potential to be reduced-risk, in each case if switched to exclusively as compared to continuing to smoke cigarettes.

Our diverse portfolio of PRRPs



Vapour products (e-cigarettes)*

Handheld, battery-powered devices that create a vapour to inhale. The most popular tobacco-free alternative, vaping is estimated to be around 95% less harmful than smoking, according to Public Health England.

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Tobacco heating products (THPs)

THPs heat but don't burn tobacco, so no smoke (which is a key source of toxicants) is produced. Research indicates by heating tobacco rather than burning it, THPs can have the potential to be reduced-risk compared to smoking.

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Oral products* Oral products usually contain tobacco, but there is no burning. There is strong epidemiological evidence that switching to snus completely reduces risk significantly, compared to smoking.

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* Our vapour product Vuse, and oral products Grizzly, Camel Snus and Kodiak, which are only sold in the U.S., are subject to FDA regulation and no reduced-risk claims will be made as to these products without agency clearance.

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66 At BAT, we're committed to transforming tobacco by providing consumers with satisfying alternatives to smoking."



After 37 years at BAT, eight of those as chief executive, I will retire in April 2019. I have always been proud of our commitment to harm reduction. It's something that we have been dedicated to for decades, and despite investing many millions of pounds, it isn't something that's been easy to achieve.

However, recent years have brought the most dynamic period of change our industry has ever encountered and there have been huge advancements in the field of tobacco harm reduction. An unprecedented confluence of technology, societal change and public health awareness means that consumers now have access to a much broader range of alternatives. Many international experts believe these products can be less risky than smoking – vapour products, for example, are estimated to be 95% less harmful.

At BAT, I am particularly proud that so much progress has been made since 2012, when shortly after taking over as CEO we articulated a new vision – to be the best at satisfying consumer moments in "tobacco and beyond" – placing consumers and our desire to lead the development of reduced-risk products right at the centre of our strategy. This marked the start of what has become the most meaningful transformation of BAT in our 116-year history.

Since this milestone we have radically changed our approach to R&D to deliver a

range of potentially reduced-risk products. Collectively we refer to these products as PRRPs and we now have these available in a total of 28 countries globally. With the acquisition of Reynolds American in 2017 we significantly increased both our geographic reach and our prospective consumer base. We are a stronger, truly global company, with an innovative, even more diverse portfolio of PRRPs.

A diverse portfolio we continue to be proud of

Our range today includes vapour products and tobacco heating products, as well as oral tobacco and nicotine products. It is clear to me that consumers looking to switch to alternative products need to go through a journey and a large part of this is about having access to the right alternatives. Without the right products, tobacco harm reduction will never be a reality, which is why our approach is centred on developing an outstanding product portfolio.

I've always held the belief that a range of products is essential because consumers themselves are different, with a wide range of preferences and needs. A one-size-fits-all approach isn't going to work: to maximise the potential for PRRPs to contribute to harm reduction, we need to provide alternative products to suit the different taste palates of smokers, in formats they find accessible, in a cleaner and hassle-free way.

Our role in tobacco harm reduction is clear but we still have a long way to go. We are investing significantly in developing and commercialising our product range and have a strong pipeline of innovative products across all categories – with several innovative product launches planned for 2019.

However, we are not just investing within our business, we are increasingly looking at disruptive technology solutions that can help consumers find the right alternative PRRP, one which will really work for them and one that they will want to switch to only then will we be able to help reduce the harm tobacco causes in society.

Building trust through science

PRRPs are still relatively new products and it is essential that consumers believe and understand the reduced risk profile of any product and can make an informed choice. To do this, we must have a robust scientific framework in place. Equally, we also need to provide the results of our scientific assessments to all interested stakeholders so that regulators can also understand the reduced-risk potential and support the growth of the category in order to contribute to tobacco harm reduction. I'm proud to say we are at the forefront of scientific research and always share our findings openly and transparently.

Facilitating responsible growth of PRRPs

And yes, I am delighted at the progress we have made but there are challenges too. Often ones we can't resolve alone. These products can only meet their potential if the right regulatory and market conditions are in place. Stakeholders from across government, industry and public health need to work together on creating an environment for tobacco harm reduction to be successful.

The future of harm reduction at BAT

There are still 1.1 billion smokers in the world and we are undoubtedly at the start of a long journey, but as I come to the end of my eight-year tenure as the CEO of this fantastic company, I am confident we can deliver against our commitments.

We have a clear vision and priorities in place. We are clear that we want to be the world's best at satisfying consumer moments in tobacco and beyond and we are well equipped to accelerate the transformation we have started.

And as I hand over to my successor, I know the company is in great hands and that this is just the beginning of BAT's mission to transform tobacco.

Nicandro Durante Chief Executive, December 2018

INTRODUCTION

The harm reduction journey

Tobacco-related harm reduction will only be delivered when consumers shift from a risky product – cigarettes – to less risky products. During this change, a smoker tends to go through a number of stages, asking key questions at each: below, we outline this journey towards transition, which we will discuss in more detail throughout this report.



A view from the outside

Here, Dr Saul Shiffman, a Professor of Clinical and Health Psychology, provides an expert viewpoint on tobacco harm reduction.



Biography

Dr Shiffman has been conducting behavioural research on nicotine and tobacco for 45 years, and has published over 400 scientific papers. He also serves as Senior Scientific Advisor at Pinney Associates, a global health advisory and consulting firm with a practice in tobacco harm reduction¹.

Among the notable awards he has received for his work in the field of clinical research and behavioural medicine is the Ovid Ferno Award "for breakthroughs in clinical research", awarded by the Society for Research on Nicotine and Tobacco. Tobacco harm reduction is one of the most promising public health policies available to us, with the potential to save many lives. The concept of tobacco harm reduction is simple and compelling: there is vast evidence that people smoke cigarettes – and continue to smoke them despite warnings about risk – in order to get nicotine.

But cigarette smoke doesn't just contain nicotine: it contains thousands of compounds produced by the process of burning, many of which are known to be harmful to human health. The idea of tobacco harm reduction is to encourage smokers who are not going to quit to migrate to products that deliver nicotine without those toxic combustion products.

G The important claim for PRRPs is that they are much less harmful than smoking, not that they are completely safe."

Yet, adoption of PRRPs by smokers could be faster. Adoption is impeded by widespread misunderstandings about PRRPs. Too many members of the public, health professionals and policy-makers believe that PRRPs such as oral tobacco, vapour products and tobacco heating products are at least as harmful as conventional combusted cigarettes – contrary to evidence. These misconceptions are fed, in part, by efforts from tobacco harm reduction opponents to warn people away from PRRPs.

But perhaps a more important issue is the failure – by researchers, media outlets and consumers themselves – to distinguish

absolute risk from relative risk. We are daily bombarded with stories about one potentially harmful constituent or another found in a PRRP. But the reports, even when scientifically accurate, too often completely lack context, failing to compare the level of exposure from PRRPs to that from smoking or to place the amount of exposure in context. The important claim for PRRPs is that they are much less harmful than smoking, not that they are completely safe. Helping the public and key stakeholders develop an accurate understanding of harm reduction and the science of PRRPs would go a long way towards promoting adoption of PRRPs by smokers who would otherwise continue to smoke. Industry, academia, health NGOs and governments all have important and complementary roles to play in educating these constituencies to correct misperceptions.

Product innovations and improvements also have a key role in promoting migration from smoking to PRRPs. Although harm reduction can motivate switching to PRRPs, smokers may find it hard to make the switch unless the tobacco harm reduction alternatives are satisfying enough to substitute for cigarettes. Whether they involve better nicotine delivery or a better sensory experience, product innovations will be crucial in promoting migration from smoking to PRRPs.

The recently developed PRRPs – e-cigarettes and tobacco heating products – have made a great start. But even better products are surely in our future. Industry has the key role to play in developing innovative PRRPs, while government regulators also have key roles in enabling – or at least not impeding – product innovation, to the benefit of public health.

OUR PRRP PORTFOLIO

own taste.

Vapour products

A vapour product, or e-cigarette, heats a liquid (called an e-liquid, usually containing nicotine) and creates a vapour to be inhaled. These contain no tobacco and no combustion takes place.



Closed-system devices

These have a closed cartridge containing the e-liquid, which comes in a wide range of flavours and nicotine strengths. Consumers purchase replacement cartridges to continue using the device. With frequent innovations including more powerful batteries, this hassle-free way to vape is becoming increasingly popular.

Our flagship brands are Vype, globally, and Vuse*, our leading brand in the U.S.

Vaping is transforming tobacco

52% of the 3.2 million adult

Find out more about how the UK policy framework has enabled this on page 17.

75–80 million adults



- Vuse, which is only sold in the U.S., is subject to FDA regulation and no reduced-risk claims will be made as to any product under this brand without agency clearance.
- ASH, "Use of e-cigarettes (vapourisers) among adults in Great Britain", September 2018. 1
- 2 The House of Commons Science and Technology Committee, Seventh Report of Session 2017–2019 on e-cigarettes, July 2018.
- BAT estimates, as presented at the Analyst Briefing on 16 October 2018. Available to download at http://www.bat.com/investorpresentations 3

EMPLOYEE VIEWPOINT

An innovative vaping experience: the new ePen 3

66 Since our ePen was launched in 2014, we have been looking for opportunities to make this convenient and simple way to vape even better for the consumer. And with one of our latest innovations, the Vype ePen 3, I think we've definitely achieved that.

It has a sleek closed-system design, coupled with a powerful battery. The flavour pods are easy to replace, featuring click-in and -out pods that allow users to change flavour and nicotine levels in one simple step. Plus, all pods have a no-spill design for an enjoyable, and no-mess, vaping experience.

But it's not just developers like me who love the product. Since its launch in the UK, initial results show ePen 3 has already been a success with vapers too!"



Independent evidence on the reduced-risk potential of vapour products

There is growing consensus among many public health bodies and academics that vapour products can have a significantly reduced risk profile compared to smoking. Public Health England in the UK estimates these products are "95% less harmful than smoking"⁴. Other third-party science and research supporting the significantly reduced-risk potential of these continue to grow around the world.

Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping." Public Health England⁵



66 There is conclusive evidence that completely substituting e-cigarettes for ... cigarettes reduces users' exposure to numerous toxicants and carcinogens present in cigarettes."

for ... cigarettes reduces users' exposure to numerous toxicants and carcinogens present in cigarettes." The U.S. National Academies of Sciences, Engineering, and Medicine⁶

G Vaping is less harmful than smoking. Completely replacing cigarettes with a vaping product will significantly reduce a smoker's exposure to toxic and cancer-causing chemicals." *Health Canada*⁷

A CLOSER LOOK

Canada's evidence-based approach to vaping regulation

The Canadian Federal Government has established itself as a model for pragmatic and evidence-based regulation of PRRPs. The catalyst for this was the Government's open acknowledgement of the potential vapour products can have in harm reduction and the recognition that any policy framework must be science-led and based on input from a variety of expert stakeholders.

After a bill to make vapour products legal for sale was introduced into parliament in 2016, the Government ran a consultation with input from health experts, tobacco harm reduction advocates and manufacturers. It also formed a scientific advisory board and commissioned a science-based review to provide recommendations on the federal legislative framework for vapour products. As well as contributing our technical expertise in the consultation process, BAT's Chief Scientific Officer went to Canada to share the science behind our products and answer unfiltered questions from the media and the public. In the same spirit of transparency, we opened our R&D centre in Southampton to interested stakeholders to help build awareness around the science behind PRRPs and the quality standards we apply.

After a two-year process of consultation and scientific review, the bill became law in May 2018. While the full suite of federal regulations have not yet been introduced and there are still challenges in aligning federal and provincial law, consumers in Canada now have access to vapour products, including our own Vype ePen 3.



- 4 Public Health England, E-cigarettes: a new foundation for evidence-based policy and practice, August 2015.
- 5 McNeill, A., Brose, L.S., Calder, R. et al. "Evidence review of e-cigarettes and heated tobacco products 2018". Public Health England (2018).
- 6 U.S. National Academies of Sciences, Engineering, and Medicine. "Public health consequences of e-cigarettes" (2018).
- 7 Health Canada, Overview of Canada's Tobacco Strategy, 31 May 2018.

OUR PRRP PORTFOLIO

Tobacco heating products (THPs)

A THP heats tobacco enough to release nicotine and flavours, but not high enough to burn it. This creates an aerosol to be inhaled, which contains nicotine, glycerine, flavourings and water – but not many of the toxicants of tobacco smoke.



Where are our THPs available?



EMPLOYEE VIEWPOINT Creating a satisfying product through precision design

66 The chemical emissions profile – and taste – of tobacco changes at different temperatures, so one of the biggest challenges for my team when they were developing glo was how to deliver a greattasting sensory experience at a lower temperature than when smoking a cigarette.

And glo was designed to do exactly this. To make sure it delivers the very best experience, it uses zonal heating to prevent the tobacco stick getting heated all at once – it's like a precisely engineered mini-oven.

Of course it was also really important that we designed a high-quality, compact device that meets the needs of modern consumers and I think we're all proud of the final product: it has smart electronic controls, the flavours are delivered consistently, and it gives the user a satisfying and enjoyable experience."



Independent evidence on the reduced-risk potential of THPs

Research indicates that by heating tobacco rather than burning it, THPs can have the potential to be reduced-risk compared to smoking.

Although most of the research to date has been conducted by the industry, we are encouraged to see more independent research – that broadly agrees with our findings – and would welcome further independent reviews. According to a study commissioned by the *German Federal Institute for Risk Assessment* (*BfR*)^{*t*}, THP emissions contain "markedly reduced" levels of major carcinogens compared with cigarettes, while delivering comparable levels of nicotine.

The UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) references a 50–90% decrease in some of the harmful and potentially harmful compounds (HPHCs) in the aerosol generated by heatnot-burn devices which the user would be exposed to, compared to HPHCs from cigarette smoke.² 66 As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn tobacco products." The UK COT²

A CLOSER LOOK

The Japanese experience

Through THPs, the tobacco consumption landscape in Japan is changing very quickly. In a market that until very recently only sold cigarettes, we estimate that THPs now account for around 22% of the total tobacco market.

We launched our flagship THP glo in Sendai, Japan, in December 2016, followed by a national roll-out in October 2017. Since then, we have been working hard to support our consumers to help them to get the most out of their experience of glo. With THPs still being relatively new to the market, we believe it's crucial to provide smokers with this support, to educate them on the device and to provide after-care for their queries. We do this through our glo stores as well as through engagement with other retailers that sell glo on our behalf. This has been a new model for us but is proving to be successful by ensuring consumers understand the product and have the support they need on their journey of switching to glo.

And we are pleased glo has been received well in Japan – its market share has grown to 4.4% as of October this year, up from 3.3% at the start of the year. As well as its high-tech, potentially lower-risk way to consume tobacco, we believe that glo has been successful because of its ease of use, offering consumers a more considerate way of using tobacco with far less impact on their surroundings. With new product launches delivered in 2018 and new innovations planned, this is a growth we hope to see continue into next year.



Mallock, N., Böss, L., Burk, R. et al. "Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks", Arch Toxicol (2018) 92: 2145. https://doi.org/10.1007/s00204-018-2215-y.

2 Statement on the toxicological evaluation of novel heat-not-burn tobacco products, The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), Department of Health UK, December 2017. **OUR PRRP PORTFOLIO**

Oral products

Oral products* span different categories, from conventional snus and snuff to innovative all-white oral pouches, as well as medicinal nicotine replacement therapy products – each addressing the preferences of different consumers. The tobacco content of oral products differs, with some containing tobacco, some at lower levels, and others none at all.



* Grizzly, Camel Snus and Kodiak, which are only sold in the U.S., are subject to FDA regulation and no reduced-risk claims will be made as to these products without agency clearance.



The Swedish experience

There is substantial evidence that using snus exclusively has significantly reduced risk compared to smoking¹, and experts often speak of the 'Swedish experience' in the context of successful harm reduction.

In Sweden in the 1970s and 1980s, there was a gradual shift from cigarette smoking to snus use, particularly among Swedish men, with a reduction in smoking-related disease rates seen decades later.

Today, Sweden's overall daily consumption of tobacco is close to the daily EU average, but it has by far the lowest rates of smoking in Europe. Sweden also has the lowest rates of tobacco-related diseases. Many authorities, including those outlined below, have cited the widespread availability of snus as a key factor in Sweden's move away from cigarettes.

Independent evidence on the reduced-risk potential of oral products

A study by Rodu and Cole shows "that snus use is inversely correlated with cigarette consumption among men in Sweden, Swedish-style snus has resulting in the lowest lung cancer mortality a compelling amount of rates (LCMRs) in Europe for most of the past epidemiological data that 50 years³." Another study notes Sweden also shows substantially less displays one of the lowest oral cancer rates health risks than smoking². in the world⁴. **66** ST [smokeless tobacco] products are much cleaner and less hazardous than cigarettes. Their use could reduce harm to smokers if they switched entirely to these products. This appears to be the case with snus use in Sweden." Prof Neal Benowitz, an internationally recognised expert in tobacco addiction5

- "Harm reduction in nicotine addiction: helping people who can't quit." Tobacco Advisory Group of the Royal College of Physicians. Royal College of Physicians, 2007. 1
- Nutt, David J., Lawrence D. Phillips, David Balfour, et al. "Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach." European Addiction 2 Research 20, no. 5 (2014): 218–25. doi:10.1159/000360220.
- Rodu, B., Cole, P. "Lung cancer mortality: comparing Sweden with other countries in the European Union." Scand J Public Health. 2009 Jul, 37(5): 481-86. 3 doi: 10.1177/1403494809105797. Epub 2009 Jun 17.
- "Oral Cancer Death Rate by Country." World Life Expectancy. Accessed April 10, 2018. https://www.worldlifeexpectancy.com/cause-of-death/oral-cancer/by-country/. 4
- Benowitz, N. L. "Smokeless Tobacco as a Nicotine Delivery Device: Harm or Harm Reduction?" Clinical Pharmacology & Therapeutics 90, no.4 (2011): 491-93. doi:10.1038/ 5 clpt.2011.191.

A CLOSER LOOK

A more innovative way

In a fast-moving world that continuously calls for improvement and variety, the demand for innovative oral products continues to grow.

This is where EPOK comes in. It contains specially processed tobacco, and offers consumers a smoke-free and hasslefree experience.

<u>G</u> EPOK has seen significant growth in Sweden and Norway, where it helped BAT achieve a market share of 12% and 8% respectively by mid-2018."

Unlike Swedish-style snus, which has traditionally appealed more to men, EPOK is more likely to appeal to men and women equally, which will increase its potential to contribute to tobacco harm reduction.



The importance of innovation for harm reduction

Adult smokers are more likely to switch to products that have reduced-risk potential (PRRPs) if they can find one that gives them a satisfying experience. This is why innovation is central to making harm reduction a reality.

We have embraced this challenge and look to create high-quality products in which adult smokers will find a satisfying and enjoyable alternative to smoking.

Technology today is changing rapidly, and we are now working in an increasingly dynamic consumer and technology landscape. To make sure we stay ahead of the curve, we are investing heavily in transforming our company from a manufacturer of a single product into one that harnesses the power of innovation to offer consumers a diverse portfolio of PRRPs.

We are always on the lookout for the next cutting-edge technology to be able to offer adult consumers more choice: more advanced, better performing, appealing products with reduced-risk potential.

We are doing this through our significant investment in disruptive technologies to drive innovation, while transforming our workforce as we continue to bring together a powerful combination of skills and building the capabilities required for inventing and developing exceptional products.

At the same time, it is essential that we continue to manufacture these innovative new products to the highest quality and safety standards and consumer product safety remains critical to our approach.



Carlista Moore Condé Head of THP Product Development



Transforming our workforce

EMPLOYEE VIEWPOINT New skills to drive innovation

66 I've only recently joined BAT but have over 20 years of experience in developing consumer products. Throughout my career, I've had many opportunities to drive innovation and create great products that consumers love – but never at such a transformational scale and never backed up by such phenomenal science as we have at BAT.

Our products, by their nature, are the type that consumers interact with all the time, and it's my job to translate varying consumer needs into an inspiring product design. To do this, we need to develop new 'innovation muscles': new ways of thinking, drawn from more diverse backgrounds and more collaboration. To help us think differently, we are transforming our workforce and my team has already grown significantly as we bring in diverse skills and new insights. We are also changing our ways of working and increasingly bring teams and ideas together to develop new products. It's all about creating an environment that fosters innovation.

I'm particularly proud to be a part of the genuine, open and collaborative working culture here at BAT. Joining BAT's R&D team at an exciting time like this means we can all contribute personally to the development of great products which will ultimately support tobacco harm reduction."

Consumer product safety

EMPLOYEE VIEWPOINT

Ensuring exceptional product quality



C The technology around PRRPs is developing fast, and it's crucial for companies like BAT and regulators to ensure that these new products are manufactured to the highest possible quality and safety standards.

As a company, we have years of experience in consumer product safety and it's something we take very seriously. My team aims to go above and beyond legal requirements to make sure the materials and ingredients we use are the best available.

GG My team aims to go above and beyond legal requirements to make sure the materials and ingredients we use are the best available."

What does that mean in practice? In our labs, our products benefit from thousands of hours of testing before they reach the consumer, including a toxicological risk assessment of all the ingredients in and emissions from our products. We use high-quality ingredients – our e-liquids used in vapour products, for example, are manufactured mostly in the EU and use pharmaceutical-grade nicotine.

Unfortunately, not all products in the market are tested as rigorously, and that needs to change.

Universal product quality standards are absolutely essential if consumers are going to have confidence in the products and PRRPs are going to be a success. We would like to see consistent standards that:

- control what goes into these products and what comes out of them;
- ensure device safety; and
- ensure the product works in the correct way it's designed and intended to.

We are pleased by the recent regulatory developments which are establishing product standards in the UK. Guided by the European Union Tobacco Products Directive, the UK regulator has developed a set of requirements aimed at improving the safety and quality of vapour products (e-cigarettes) and the liquids used in them (e-liquids). We would encourage more regulators around the world to adopt a similar approach.

For our part, we've already worked alongside multi-stakeholder groups on the publication of the world's first voluntary standards on e-cigarettes, created by the French standards institute AFNOR and the British Standards Institute, and also on the world's first THP standard in Russia. We will continue to work with both industry and regulators to support the development of industry-wide quality and safety standards for PRRPs. We see this as one of the many things we can do to ensure the success of these products."



Building trust in our products through science

For PRRPs to support tobacco harm reduction, it's essential that their potential to be reduced-risk compared to smoking is supported by robust science. We're addressing this through our leading scientific research programme and by openly sharing our findings.

As PRRPs do not involve burning tobacco, there's broad scientific consensus that these have the potential to be significantly less risky than cigarettes. Still, to fully understand whether their use presents less risk to consumers, it's crucial to adopt a multidisciplinary approach to their risk assessment.

This is particularly important as these products are relatively new and are evolving rapidly, alongside the changes in technology and shifts in consumer demand.

Our multi-disciplinary risk assessment framework

Most PRRPs are new to the market and therefore epidemiological data, which establishes the harm reduction potential over decades of use, is not available. Instead, it's necessary to take a weight of evidence approach based on the emissions, exposure and risk levels of each product.

Firstly, we need to examine the emissions of any product and establish exactly what is in the vapour or aerosol. Next, we need to understand what happens when human cells are exposed to these emissions. Once this has been established, we can begin to assess what the long-term risk of using a particular product is. At each stage, we undertake a range of different studies that collectively make up our multi-disciplinary risk assessment framework.

Best practice standards for our scientific research

All our clinical studies are approved by the relevant independent ethics committees before initiation.

The majority of our product testing is through independent scientific laboratories and research organisations.

We submit the results of our research to peer-reviewed scientific journals, irrespective of their findings, which involves an assessment by independent experts to determine whether it is of sufficient quality to be published.

Assessing the reduced-risk potential of our products

We apply our peer-reviewed scientific assessment framework to assess the emissions, exposure and risk of our products.



Advancing science through clinical studies

We have undertaken research into emissions and exposure levels in the laboratory for many years. However, it is the field of clinical studies where we study the impact on the human body that gives us the most accurate insights into the impact of PRRPs on human health.

We have already conducted several short clinical studies, which show encouraging results on how our PRRPs may have reduced risk. For example, two five-day studies showed participants who switched from cigarettes to glo saw their exposure levels reduced to similar levels as those seen in people who have stopped smoking completely.

To expand on these, we have recently started our biggest and most complex PRRP clinical studies to date. For one year, our two upcoming studies will examine indicators of risk in groups of adult smokers who continue smoking, switch to using glo or a vapour product, or quit nicotine and tobacco product use completely. We aim to publish initial results in 2019, with the full results due in 2020.

Sharing scientific knowledge

We think PRRPs will have the biggest impact on harm reduction when good-quality science is shared openly. That's why we openly share our scientific framework and publish in journals where research findings are independently reviewed by experts through peer reviews. We also present our data at conferences and to the technical advisory committees of governments.

To date, we've published 23 peer-reviewed articles on THPs, including 13 specifically on glo, and 23 on vapour products, with 15 of these focusing solely on ePen. In addition, we have published five manuscripts that review vapour products and THPs jointly, for their reduced-risk potential as a category. To date, we have published over 50 papers and manuscripts. These notably include a series for Vype ePen¹ – the most comprehensive dossier of scientific data published on a single vapour product to date – as well as 13 papers on our flagship THP glo² and a five-step approach for assessing THPs³.

EMPLOYEE VIEWPOINT Science keeping pace with speed of innovation



Dr Marianna Gaca Head of Pre-Clinical Assessment 66 In today's fast-moving technology landscape, we are able to develop new products faster than ever.

But this presents us with a challenge – the clinical studies needed to examine reducedrisk potential can take up to five years to complete, much longer than the typical three- to six-month product innovation cycle. This makes it difficult for my risk assessment team to study the effects of each individual product.

To help us address this, we've looked to other industries, such as pharmaceuticals, who've faced this issue in the past and who now use an abbreviated set of scientific tests alongside a reference product each time a technology is updated. It's an approach called 'bridging'.

We've been working hard to see how we can adapt this approach for our own industry as we believe that with the right science and regulation in place, PRRPs could be riskassessed based on previous versions.

So, what have we done to progress this? My team has developed a series of steps to determine whether bridging is appropriate for a product and established the assessments that could be used. We've shared our knowledge on these scientific assessment tools, scientific data and findings on how PRRPs can be risk-assessed compared to GG It is an exciting time for all of us working in toxicology at BAT – it feels like our science is really making a difference."

a reference product on a collaborative wiki web-based platform. The wiki serves as a component of the OECD's efforts on building a toxicological knowledge framework, providing a data repository and an open-source interface for the wider science community. We hope this will contribute to how OECD member countries review relative risks of PRRPs.

If accepted by the scientific community and regulators, these tests can be applied to the risk assessment process of a new generation of PRRPs and help assess their potential without time-consuming clinical studies.

Even better, by developing this new approach we are also advancing the field of non-animal testing and I'm immensely proud that in 2017 our initiative was recognised by an award from the PETA International Science Consortium.

It is an exciting time for all of us working in toxicology at BAT – it feels like our science is really making a difference."

- 1 Murphy, J. et al. (2017). Assessing modified risk tobacco and nicotine products: Description of the scientific framework and assessment of a closed modular electronic cigarette. *Regulatory Pharmacology and Toxicology 90: 342–57.*
- 2 These include: Proctor, C. et al. (2017). Special Issue: Assessment of tobacco heating product 1.0. *Regulatory Toxicology and Pharmacology* 93: 1–104. Other publications are available from www.bat-science.com/library.
- 3 Eaton, D. et al. (2018). Assessment of tobacco heating product THP1.0. Part 2: Product design, operation and thermophysical characterisation. Regulatory Toxicology and Pharmacology 93: 4–13.

A growing body of independent evidence

Research conducted by the industry isn't always enough to convince all stakeholders around the reduced-risk potential of PRRPs.

Fortunately, there is also a growing body of independent evidence that demonstrates the reduced risk of PRRPs relative to cigarettes and is helpful in addressing some of the fundamental questions people have around their use.



1 New Zealand Ministry of Health https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco.

- 2 Swiss Federation of Addiction Professionals, "Position of the federation of addiction professionals on vaping" (Translated from "Position de la fédération des professionnels des addictions sur le vapotage"), November 2017. https://www.grea.ch/sites/default/files/171019_positionspapier_vapotage_0.pdf.
- 3 "Vaping" Government of Canada https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping.html.
- 4 "Nicotine without smoke: Tobacco harm reduction" Royal College of Physicians, April 2016.
- 5 "FDA's Nicotine and Tobacco Regulation and the Key Role of Regulatory Science" Remarks by Scott Gottlieb, M.D., June 18 2018. *Note: ENDS stands for electronic nicotine delivery systems, including e-cigarettes.
- 6 "Smoking: Harm Reduction" The UK National Institute for Health and Care Excellence, 2013.
- 7 Drope, J., Cahn, Z., Kennedy, R., Liber, A.C., Stoklosa, M., Henson, R. and Douglas, C.E. Key issues surrounding the health impacts of electronic nicotine delivery systems (ENDS) and other sources of nicotine. CA: a cancer journal for clinicians. 2017 Nov, 67(6): 449–71. Please note the research was published with the following disclaimer: "The contents of this article are the sole responsibility of the authors and do not necessarily represent the positions of the American Cancer Society."
- 8 Public health consequences of e-cigarettes, National Academies of Sciences, Engineering, and Medicine, Washington, DC: The National Academies Press, January 2018.



a gateway product. In fact, many studies have shown an association between increased use of vapour products and a decline in smoking rates, including among youth. All the UK evidence, and almost all the international evidence, on the use of e-cigarettes by children and young people to date indicates that concerns about e-cigarettes helping to recruit a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded." UK Royal College of Physicians¹²

GC Surveys across the UK show a consistent pattern: most e-cigarette experimentation does not turn into regular use, and levels of regular use among young people who have never smoked remain very low," according to a study of 10,000 teenagers, published at the University of Stirling¹³. **GG** There is no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use." *The Centre for Addictions Research of BC*¹⁴

- 9 Simonavicius et al. What factors are associated with current smokers using or stopping e-cigarette use? Drug and Alcohol Dependence 173 (2017) 139–43.
- 10 Tobacco harm reduction in the real world: has the availability of snus in Norway increased smoking cessation? Karl Erik Lund, Norwegian Institute for Alcohol and Drug Research, Oslo, Norway DOI: 10.1108/DAT-02-2013-0006.
- 11 McNeill, A., Brose, L.S., Calder, R. et al. "Evidence review of e-cigarettes and heated tobacco products 2018." A report commissioned by Public Health England, 2018.
- 12 "Nicotine without smoke: Tobacco harm reduction" Royal College of Physicians, April 2016.
- 13 Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017, Bauld, L. et al., International Journal of Environmental Research and Public Health, August 2017.
- 14 O'Leary et al. (2017). Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices: Victoria, BC: Centre for Addictions Research of BC.

The importance of effective regulation and responsible growth

Along with the industry, governments and the public health community have a key role to play in maximising the potential for PRRPs to contribute to harm reduction. For these products to be a success, they must be supported by effective regulatory and policy regimes that enable responsible growth and promote informed consumer choice. This must then be complemented by responsible practices by the industry.

There are already markets, like the UK, where regulators and ministries of health have been successfully using some PRRPs in smoking cessation campaigns. In other markets, such as Canada and New Zealand, we are seeing governments overturn bans on PRRPs as the science increasingly points to their value as an alternative to smoking.

This is resulting in policy and regulation that allows PRRPs to be available in markets under strict quality and safety standards and where the benefits of switching to PRRPs can be communicated effectively to consumers. However, in many parts of the world, governments are still unclear about how PRRPs should be regulated.

The need for effective regulatory framework

For PRRPs to contribute to tobacco harm reduction, they need to be widely available and this requires governments to establish an effective regulatory framework.

This framework should ensure alternative products are available and affordable, and their potential benefits and risks can be clearly understood, and differentiate between products and tax them relative to their risk.

Governments, the industry, public health experts and the science community all have a role to play in contributing to the development of an effective regulatory framework, and ensuring PRRPs can deliver on their potential to reduce risk for smokers, as outlined below.

What is the industry's role in developing regulation and policy?

The most effective regulation requires input from all stakeholders. As a company with detailed knowledge of the products and their categories, it's important for us to give our view on proposed legislation and the policies that impact both the products and their subsequent take-up by consumers.

We are often invited by governments and other bodies to provide technical data and research, and to bring our expertise to the process of drawing up new policies.

Some examples of this include our work with the British Standards Institution (BSI), its French counterpart AFNOR, the International Organization for Standardization (ISO) and the European Union's standards body (CEN) to develop new quality and safety standards for vapour products. The British and French standards were published in 2015 and 2016, respectively. We also contributed to the development of ISO's vaping standard and CEN's guidance document on vaping aerosol measurements, both published in September 2018, with another CEN standard expected early 2019.

In situations such as this, where we have been able to contribute to policy development, we believe we've made a valuable contribution and that the multi-stakeholder process has ensured that appropriate frameworks are in place to protect consumers while ensuring marketing freedoms exist. It's something we want to see more of and we are always open to new ways to collaborate.



A CLOSER LOOK

The UK's success in smoking cessation through effective policy

The UK has the second-lowest rate of smoking in Europe¹ and is the largest vaping market. This is an example of what can be achieved when regulators and public health bodies work together to support growth of PRRPs and deliver harm reduction.

Major reports on the reduced-risk potential of vapour products by Public Health England (PHE) and the Royal College of Physicians laid the ground for an open public debate on smoke-free nicotine products. Combined with a progressive approach to regulation, this is helping to contribute to the UK's success in turning away from cigarettes. Today, there is conversation and collaboration across public health bodies, the House of Commons and even antismoking NGOs on the potential of PRRPs to support smoking cessation.

The UK Government conducts annual reviews of the evidence on e-cigarettes, and the House of Commons Science and Technology Committee has recommended extending these to THPs. There is also support for a long-term research programme on THPs to be overseen by PHE and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. However, there is still a need for a review of regulatory barriers, notably for snus – a product with epidemiological evidence for its reduced risk relative to cigarettes. We are encouraged by the call for an evidence-based assessment of the case for discontinuing the ban on snus, which was recently noted as a key recommendation by the House of Commons Science and Technology Committee².

How should PRRPs be regulated?

To support the growth of these important products and contribute to a reduction in projected tobacco-related harm across society, an effective regulatory framework is needed. We believe an effective regulatory framework for PRRPs should address:



1 Press Association, Smoking rate in UK falls to second-lowest in Europe, 15 June 2017, https://www.theguardian.com/society/2017/jun/15/smoking-rate-in-uk-falls-to-second-lowest-in-europe.

2 The House of Commons Science and Technology Committee, Seventh Report of Session 2017–2019 on e-cigarettes, July 2018.

Responsible marketing of PRRPs

It's essential that these products are not marketed to youth. In markets where there aren't sufficient standards in place to ensure this is the case, we welcome industry-wide responsible marketing and youth access prevention standards.

Communicating the benefits of PRRPs widely to consumers will be integral to the success of these products, to enable more smokers to switch. As well as 'what' should be communicated, responsible marketing of PRRPs needs to consider the 'how'.

The need for responsible communication

The facts about the reduced-risk potential of alternative products (PRRPs) need to be communicated carefully to consumers, in order for them to make informed choices about their health and to be encouraged to switch to these products.

Independent research – including from public health bodies – shows many smokers are still sceptical about PRRPs and "some even falsely believe these are as harmful as smoking"¹.

Independent research shows...

GG Four out of 10 smokers wrongly think nicotine causes most of the tobacco smoking-related cancer, when evidence shows nicotine actually carries minimal risk of harm to health ... E-cigarettes do not contain tar or carbon monoxide, two of the most harmful elements in tobacco smoke." Martin Dockrell, Tobacco Control Programme Lead for Public Health England¹.

Researchers from the University of Wisconsin's Center for Tobacco Research and Intervention and UCSF's Smoking Cessation Leadership Center have recommended to "communicate intelligently about harm reduction – all nicotine-containing products are not equal – the public health focus should be to eliminate combustible tobacco products, even if it means some individuals who give up combustibles will continue to use indefinitely FDA medications, e-cigarettes, or smokeless tobacco products"².

What does responsible marketing mean to BAT?

Aiming our marketing only at adult smokers has long been a fundamental requirement of our suite of International Marketing Principles (IMPs). Given the importance of PRRPs, we have recently brought together all our individual standards under one set of principles. At its heart is our commitment to never market our tobacco and nicotine products to children.

Social media is now much more accessible and widely used. If we are going to make adult smokers aware of PRRPs, the industry needs to be able to communicate via the channels that adult smokers are using, including social media.

We are clear that social media can only be used for activities that do not involve the advertising of any of our cigarette brands. Where we do use social media influencers for our PRRPs, we have strict controls in place to ensure our partnerships are appropriate, and only ever targeted at adults. To this end, we use analytic tools to ensure that followers and audiences of these influencers are majority-adult.

We also have a digital marketing toolkit in place that includes in-depth guidance to help our markets apply our marketing principles online, including where we have e-commerce websites. This covers content standards, use of social media and search engines, and a requirement to ensure robust age verification.



- 1 Martin Dockrell on *Public health matters: Clearing up some myths around e-cigarettes*, https://publichealthmatters.blog.gov.uk/2018/02/20/clearing-up-some-mythsaround-e-cigarettes, 20 February 2018.
- 2 Michael C. Fiore et al. Smoke is the Chief Killer: Clinical and Policy Strategies that Target Combustible Tobacco Use, September 2015.

LOOKING AHEAD

Shaping the future for harm reduction

As our Group Scientific and R&D Director, Dr David O'Reilly leads our product innovation and science teams. Here, he shares his views on the transformation of our industry and what it means for BAT.



What does the future of tobacco harm reduction look like for BAT?

I'm excited by today's dynamic, evolving consumer and technology landscape. Innovation is at the heart of BAT today. We already have a remarkable range of PRRPs in our portfolio and have exciting ones in our pipeline that will push the boundaries.

Our new vapour product, the Vype iSwitch, is based on a new-to-world technology called Pure Tech. This uses a metal plate technology, marking the first time we've moved away from the conventional coil and wick for heating the e-liquid. We believe this will revolutionise vaping by providing superior satisfaction, and with even less toxicants than other vapour products.

Looking at tobacco heating products (THPs), we will be launching a new and improved version of glo as well as a smaller version of the device – both developments were guided by consumer preference research. We have plans to bring a completely redesigned version of iFuse to the market next year.

If BAT is serious about harm reduction and transforming tobacco, why don't you stop selling cigarettes?

It is clear that cigarettes will remain a key part of our business for many years to come and will continue to provide a vital source of investment for our PRRPs.

We don't believe that stopping cigarette sales now would be commercially viable or practical. It's trickier than it sounds: the ongoing consumer demand for these products would either transfer straight to our competitors or, even worse, to the black market; and, in many markets, there are still real regulatory obstacles to launching PRRPs.

This is why, alongside our commitment to the transformation of our business, we also remain committed to our combustible tobacco business during this transformation.

66 We already have a remarkable range of PRRPs in our portfolio and have exciting ones in our pipeline that will push the boundaries."

Why don't you sell PRRPs in more markets?

We're 100% committed to PRRPs. Our PRRPs are already available in 28 markets, and we are launching in as many markets as quickly and practically as we can – our priority is markets where there is the highest potential, such as those with the right regulatory framework and consumer dynamics in place. We work hard to get the right mix of communication, product and price, and have a 'test and learn' strategy before we launch anywhere.

However, in many markets, local laws simply don't permit companies to launch PRRPs, even though there is growing evidence in countries such as the UK and U.S. that these products are likely to be much less risky than cigarettes. This is why a supportive regulatory environment is crucial to maximise the potential of these products to contribute to harm reduction.

Will your PRRPs have an impact on tobacco farmers?

Although we are very confident about the growth of our PRRPs, for the foreseeable future we don't anticipate their success to immediately impact the farmers we work with. It's important to remember that our THPs use high-quality processed tobacco leaf and our vapour products rely on the extraction of nicotine from tobacco plants. And of course, as I've already outlined, a significant proportion of our business will also remain in cigarettes for many years.

How can the PRRPs fully achieve their potential to support harm reduction?

Our ability to innovate, our transformed R&D team, as well as our long history of expertise in all aspects of nicotine and tobacco set us apart. We are fully committed to transforming our business and industry, and to make a real difference in realising the potential of our PRRPs in contributing to tobacco harm reduction.

I think it's vitally important for adult smokers to make informed choices to switch, based on sound advice from public health professionals. The adoption of PRRPs can be slowed down if they do not know about these products or are misinformed about them.

For our part, we will continue to deliver exceptional products and contribute to the wider tobacco harm reduction debate by developing robust scientific risk assessment frameworks and openly sharing our science.

LOOKING AHEAD

Our commitment to tobacco harm reduction

We believe that offering a broad range of enjoyable alternatives to smoking is the right approach to encourage consumers to switch away from smoking in significant numbers.

As we transform our products, our business and the industry, we will:

Continue to invest in the development and commercialisation of a range of enjoyable alternatives to cigarettes that have the potential to be significantly less risky than smoking.

WHAT WE'RE DOING

1

- We are launching PRRPs in new markets as fast as we can, while already having vapour products, THPs and oral products in markets across the world.
- We will continue to unlock new innovation opportunities, develop and refine consumer insight techniques and strengthen our innovation capabilities.
- As we transform our business, we will ensure we have the right expertise and skills to help us harness the power of innovation.

We will continue to unlock new innovation opportunities, develop and refine consumer insight techniques and strengthen our innovation capabilities.



Research the relative risks of our
PRRPS to smoking, and publish and invite independent scrutiny of our science.

WHAT WE'RE DOING

- We will embark on further research into the impact of the aerosols on consumers as well as the surrounding environment, and publish the results over 2019.
- We will conduct a long-term in-vitro study of human cells exposed initially to tobacco smoke and then switched to either glo emissions or air, and publish the results in 2019.
- We will conduct two 12-month clinical studies to assess how reductions in exposure may result in reduced long-term health risks for both vapour products and THPs. We aim to receive first results in 2019, and publish these in 2020.
- We will also publish the results of population modelling research conducted in Japan, looking at the large-scale impact of THP use nationally.

We have embarked on two 12-month clinical studies to assess how reductions in exposure may result in reduced long-term health risks for both vapour products and THPs. We aim to receive first results in 2019, and publish these in 2020.





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Engage with regulators to raise awareness about the potential benefits of PRRPs.

WHAT WE'RE DOING

3

- We will continue to provide technical data and research to bring our expertise into the process of drawing up new policies and regulation.
- We will continue to be involved in the multistakeholder groups that are developing product quality and safety standards for vapour products and THPs at national or international level.
- As we participate in external conferences and meetings, we will continue to make all the material we present publicly available via **bat-science.com**.

As we participate in external conferences and meetings, we will continue to make all the material we present publicly available via **bat-science.com**.



Responsibly market our PRRPs to enable adult consumers to make informed decisions.

WHAT WE'RE DOING

4

- We will continue to adopt the highest standards of responsible marketing, and be transparent about our approach. In 2019, we will roll out our updated International Marketing Principles (IMPs), which bring together all our individual responsible marketing standards under one set.
- We aim for 100% adherence to our IMPs, and our global Youth Access Prevention (YAP) Guidelines. We will continue publishing our performance against these goals as part of our annual Sustainability Report, including if any breaches of our IMPs have been established, and the percentage of markets undertaking YAP activities.
- We will continue to use our digital marketing toolkit, which provides guidance to our markets in applying our IMPs online, such as for the use of social media and to ensure robust age verification where we have e-commerce websites.

We aim for 100% adherence to our International Marketing Principles (IMPs), and our global Youth Access Prevention (YAP) Guidelines.



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More detailed information on our sustainability agenda and initiatives.



Performance centre Progress against our goals, performance charts, Global Reporting Initiative (GRI) reporting, independent assurance statement and our response to assurance.





Sustainability Report Our sustainability strategy and the three key areas of Harm Reduction, Sustainable Agriculture and Farmer Livelihoods, and Corporate Behaviour.







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