# HARM REDUCTION The opportunity

Sustainability Focus Report 2014



# HARM REDUCTION A NEW WAY FORWARD?

## **OUR CHIEF EXECUTIVE**

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This is an exciting time to be leading British American Tobacco. We have a new Group vision to satisfy consumer moments in tobacco and beyond, and an enhanced strategy with sustainability as one of its key pillars. This reflects our commitment to building shared value for our shareholders and for society.

Harm reduction is crucial to achieving this vision: offering less risky tobacco and nicotine products helps to meet consumer demand, and so makes genuine commercial sense, while also being the right thing to do.

This is not new to BAT – harm reduction has been a strategic focus for us for a long time. But it's only relatively recently that we've seen the emergence of a whole new generation of

alternative products – with both the rise of e-cigarettes and the potential for innovative tobacco heating devices. We think these products can have the greatest consumer appeal and, therefore, could significantly help in reducing smoking-related disease.

And I think we're a business that's best placed to deliver such products – after all, we understand what consumers want, we have world-class research and development capabilities, we have robust product and quality standards, we have global reach, and we market our products responsibly.

The challenge is that these are new products which many governments are still unsure how to regulate, and there continues to be much debate about the role they can play in public health policies. We hope that the growing weight of evidence and arguments in support of harm reduction which are being made by the scientific community, the industry and public health campaigners will help to guide future decision making.

We welcome the opportunity to be part of the debate and to contribute to making tobacco harm reduction a reality."

#### **NICANDRO DURANTE**

Chief Executive, British American Tobacco November 2014



### WHAT IS HARM REDUCTION?

In the world of public health, harm reduction is about developing policies to try and minimise the negative health impact of a risky activity without stopping it entirely.

For example, advocating the use of condoms reduces the spread of sexually transmitted diseases. For tobacco, this means offering less risky alternatives to regular cigarettes for those smokers who cannot, or choose not to, give up.

The idea of tobacco harm reduction is not a new one. We've long promoted snus, a type of lowtoxicant oral tobacco, which is a proven reducedrisk product – but it lacks wide consumer appeal and availability globally. So it's only relatively recently – with the rise in popularity of e-cigarettes – that it's moved from a concept to a global reality.

That's why an increasing number of people in the scientific and public health community are now advocating harm reduction as the way forward for helping the 1.3 billion people worldwide who continue to smoke despite the known health risks. As one recent report stated: "During the past few years EC [electronic cigarettes] have been gaining popularity, primarily among smokers who want to reduce the risk of smoking."<sup>1</sup>

In practice, this could mean that as well as traditional 'stop smoking' health services, smokers who've been unable to quit are encouraged to switch to less risky products.

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The basic proposition of harm reduction is not that alternative nicotine products are harmless but that they offer reductions in risk of 95% or more compared to cigarettes, and provide a viable alternative to smokers who cannot or do not wish to guit using nicotine.

The challenge is to find an appropriate framework for realising the significant public health opportunities this offers while managing residual risks.

The importance of dispassionate presentation and interpretation of evidence, open letter to the World Health Organisation (WHO) signed by 53 leading scientists and public health experts, June 2014

However, currently only a few governments actively support this approach. There are some public health experts and organisations with concerns that not enough is known yet about the health risks of e-cigarettes and that they could undermine efforts to denormalise tobacco use. They are also suspicious of the tobacco industry's involvement in tobacco harm reduction. For example, the World Health Organisation (WHO) recently stated that the industry "can never be considered to be a legitimate public health partner or stakeholder."<sup>2</sup>

We understand that this is a contentious topic on which opinion is often divided, and that some people are sceptical about our motivations. We hope that our actions will demonstrate our continued commitment to harm reduction and that governments will carefully consider the potential benefits it can bring as part of a progressive approach to public health policy.

 Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit, P Hajek et. al., Addiction, July 2014
Electronic nicotine delivery systems, a report by WHO, July 2014

### Science

# WHAT THE INDEPENDENT EVIDENCE TELLS US

#### IT'S WIDELY ACCEPTED THAT NICOTINE IS NOT THE CAUSE OF SMOKING-RELATED DISEASES

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We have known for years that people smoke for the nicotine, but die from the smoke."

Reducing the toll of death and disease from tobacco, open letter to the WHO signed by 53 leading scientists and public health experts, May 2014

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Although nicotine per se has potent pharmacological effects (including increased heart rate and constriction of blood vessels), there is a large body of evidence that medicinal nicotine (in currently licensed forms) is not a significant risk factor for cardiovascular events, and does not cause cancer or respiratory disease."

The use of nicotine replacement therapy to reduce harm in smokers, a public assessment report by the UK Medicines and Healthcare products Regulatory Agency, February 2010

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Nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death."

Tobacco harm reduction approaches to smoking, UK National Institute for Health and Care Excellence, public health guidance 45, July 2013

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Health effects of long-term EC [e-cigarette] use are currently not known and a degree of risk may yet emerge. However, based on the data available regarding the toxicant content of EC liquid and aerosol, longterm use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders.

> Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit, P Hajek et. al., Addiction, July 2014

### EVIDENCE SUGGESTS E-CIGARETTES ARE SIGNIFICANTLY LESS RISKY THAN SMOKING

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The chemicals that make cigarettes dangerous are either absent in electronic cigarettes or present only in trace concentrations."

Should e-cigarettes be regulated as a medicinal device? P Hajek et. al., The Lancet, July 2013

#### **Relative harm scale for nicotine products<sup>3</sup>**

In a study on behalf of the UK-based Independent Scientific Committee on Drugs, a panel of global experts in the field of nicotine and tobacco research used a multi-criteria analysis to rank tobacco and nicotine products based on harm to users and harm to wider society. The study attributed a relative harm score of 100% to conventional cigarettes, while giving a score of 4% for e-cigarettes.



### STUDIES SUGGEST E-CIGARETTES CAN HELP PEOPLE QUIT SMOKING, WHILE THERE IS CURRENTLY LITTLE EVIDENCE THAT THEY'RE A GATEWAY INTO SMOKING

While it is important to control the advertising of electronic cigarettes to make sure children and non-smokers are not being targeted, there is no evidence from our research that e-cigarettes are acting as a gateway into smoking."

> Action on Smoking and Health UK, press release on e-cigarette research, April 2014

A UK study found that smokers trying to quit without professional support are around

more likely to succeed using e-cigarettes than if they use products like patches or gum, or just willpower<sup>4</sup> Many recent studies<sup>5</sup> have found that regular e-cigarette use among people who've never smoked is negligible at

Junder 1%

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There have been some suggestions that among nonsmokers, electronic cigarettes might be used as a gateway to smoking and promote smoking uptake and nicotine addiction, particularly among children and young people. However, to date there is no data supporting this claim."

*Electronic cigarettes, a report commissioned by Public Health England, May 2014* 

- 3 Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach, Prof David J Nutt et. al. on behalf of the Independent Scientific Committee on Drugs, European Addiction Research, April 2014
- 4 Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study, R West et. al., Addiction, May 2014
- 5 (a) Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit, P Hajek et. al., Addiction, July 2014; (b) Trends in electronic cigarette use in England, Smoking Toolkit Study, University College London, June 2014; (c) Use of electronic

cigarettes in Great Britain, Action on Smoking and Health, April 2014; (d) Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use: A Worldwide Survey of More than 19,000 Consumers, K E Farsalinos et. al., International Journal of Environmental Research and Public Health, April 2014; (e) E-cigarettes: Prevalence and Autitudes in Great Britain, M Dockrell et. al., Nicotine & Tobacco Research, July 2013; (f) E-cigarette awareness, use, and harm perceptions in US adults, J L Pearson et. al., American Journal of Public Health, September 2012

### Products

# NEW PRODUCTS SAFER CHOICES?

## THE RISK SPECTRUM

We are committed to developing a range of next generation tobacco and nicotine products across the risk spectrum.



#### CONVENTIONAL CIGARETTES

As well as being the most common way of consuming tobacco, cigarettes are also the most harmful. Burning any plant material like tobacco turns thousands of plant-based compounds into thousands of new compounds, some of which are toxic. Inhaling the smoke that contains these toxicants causes the overwhelming majority of smoking-related diseases.

#### TOBACCO HEATING DEVICES

These products contain blended or processed tobacco, just like conventional cigarettes, but instead of being burned the tobacco is heated to vaporise the nicotine and some tobacco flavouring compounds into an aerosol that can be inhaled. This creates fewer smoke toxicants than conventional cigarettes and therefore the potential to be less risky.

#### LOW-TOXICANT SMOKELESS TOBACCO

Snus is a type of lowtoxicant oral tobacco. It has been proven, through many decades of use in Sweden, to be substantially less risky than smoking. However, it does not have wide consumer appeal outside of the Nordic countries.

#### NICOTINE PRODUCTS

E-cigarettes and other nicotine inhalation products deliver nicotine to the user in the form of vapour. They don't contain tobacco and do not produce tobacco smoke. When manufactured to robust quality and safety standards, they are considered to be substantially less risky than regular cigarettes.

### OUR PRODUCT DEVELOPMENT

Our main focus is on developing two types of innovative products: nicotine products, including e-cigarettes; and tobacco heating devices. We think these can have the greatest consumer appeal and, therefore, the greatest potential to reduce smoking-related disease. SB

Electronic cigarettes and other novel nicotine devices can provide an effective, affordable and readily available retail alternative to conventional cigarettes. These innovations could make harm reduction a reality for smokers.

UK Royal College of Physicians, statement on e-cigarettes, June 2014

### **Nicotine products**

Our subsidiary business, Nicoventures, focuses exclusively on nicotine products. We're working to offer a portfolio of high quality next generation nicotine products that will satisfy consumers, as well as meeting any emerging regulatory requirements.

In 2013, through Nicoventures, we became the first international tobacco company to launch an e-cigarette, Vype, in the UK. Vype is just the beginning – we're investing millions of pounds, conducting scientific research and using consumer insights to further develop e-cigarettes. Nicoventures is also developing other types of nicotine products and has recently announced that Kind Consumer, its development partner since 2011, has been granted a UK medicines licence for its innovative nicotine inhaler, Voke. Regardless of the regulatory environment, product quality and safety are key for us. We have a robust approach to product stewardship, including toxicological testing, using only pharmaceutical-grade nicotine in our e-liquid and compliance with all rules relevant to manufacture, content and labelling.

As e-cigarettes are such new products, there's still a lot more research that needs to be done into the long-term effects of their use. This is something we're very much committed to and we already have a number of research projects underway. In fact, we'll be submitting the initial results of our first study to a peer-reviewed journal by the end of this year. Some of these results have already been presented at scientific conferences.

# (1) Tobacco heating devices

While new types of nicotine products have great promise, it's also really important for us to try to develop innovative less risky tobacco products.

Tobacco heating devices, also known as 'heatnot-burn', are a type of product first developed by our associate company Reynolds American in the 1980s. However, they did not gain widespread consumer acceptance.

With recent technological advancements and changing consumer preferences, we believe there is now an opportunity to develop them and produce devices that will have wider consumer appeal. They may provide an alternative tobacco experience that, in the long term, could prove to be less risky than cigarette smoking.

## Regulation

# A PRAGMATIC PUBLIC HEALTH POLICY

# Our view

KINGSLEY WHEATON

> Group Corporate and Regulatory Affairs Director

### What role does regulation play in harm reduction?

A We're working to provide high quality products to adult consumers trying to find a less risky alternative to cigarettes. So we want to get new products into the hands of as many of these consumers as possible. Regulation will be a key factor in determining how we can do this.

Overly restrictive regulations, such as advertising bans or excise taxes similar to those for regular cigarettes, could be detrimental. They could stifle the growth of new products and prevent smokers becoming aware of and accessing them.

This is why we are concerned when we see governments introducing restrictions on or bans of e-cigarettes, or considering regulating them in the same way as conventional cigarettes – as some are.

### Does that mean you don't want any regulation for new products?

No – just the opposite. We're actively advocating for regulation. But taking a 'one size fits all' approach and treating all products in the same way as traditional tobacco could be counterproductive. What's needed is a science-based approach which regulates different products appropriately, according to their risk profile.

I think there are some fundamental principles which can help underpin all new product regulation. First and foremost are product standards to ensure quality and consumer safety. Then it's about allowing the appropriate level of innovation, distribution and marketing to encourage growth. It also goes without saying that these products should in no way appeal to children and that sales should be restricted to over 18s.

# So what are you doing currently?

We're actively engaging on the issue of tobacco harm reduction and advocating our preferred approach to regulating nicotine products. We also welcome the UK consultation on e-cigarette advertising led by the Committee of Advertising Practice. We hope it will result in clear and consistent rules across all media to ensure that e-cigarettes are marketed responsibly.

In the meantime, we've voluntarily adopted a robust approach to product stewardship, appropriate warnings on all our packaging and responsible marketing directed only at adult smokers – all of which we continually monitor. This is all part of our commitment to upholding high standards for all our products, regardless of the regulatory environment.

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We need to recognise that there is a continuum of nicotine delivery products. It's not the nicotine that kills half of all long-term smokers, it's the delivery mechanism. We have to recognise some of these realities and figure out how they can impact regulatory policies."

Director of the US Food & Drug Administration's (FDA) Centre for Tobacco Products, Protecting Public Health: FDA Regulation of Tobacco Products, Legacy Foundation Warner Series webinar, June 2014

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Regulatory decisions will provide the greatest public health benefit when they are proportional, based on evidence, and incorporate a rational appraisal of likely risks and benefits."

Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit, P Hajek et. al., Addiction, July 2014

# OUR PREFERRED APPROACH TO REGULATING NICOTINE PRODUCTS

E-cigarettes and other nicotine products contain no tobacco and are considered to be significantly less risky than smoking when manufactured to robust quality and safety standards. So it makes no sense to regulate them in the same way as conventional cigarettes. We want to see a regulatory approach that puts consumer safety and product quality first, while encouraging innovation and growth.

### ENSURE PRODUCT QUALITY AND CONSUMER SAFETY

Quality standards need to be introduced covering areas such as e-liquid content, emissions testing, labelling and child proofing that will reassure both smokers and regulators.

### **ENSURE GROWTH AND CONSUMER ACCESS**

### INNOVATION TO ENSURE APPEAL

Product improvement and innovation should be supported to improve both the quality and functionality of new nicotine products.

# DISTRIBUTION TO ENSURE AVAILABILITY

To fulfil their true potential as a viable option, alternative nicotine products must be widely and easily available, both through traditional retail outlets and the Internet.

# MARKETING TO ENSURE KNOWLEDGE

The growth of these new products should be supported by responsible advertising targeted at adult smokers.

#### (a) TAXATION THAT ENABLES INNOVATION AND AFFORDABILITY

E-cigarettes are not tobacco products and so the way they are taxed needs to take this into account. Excise tax will negatively impact their potential to benefit public health.



Nicotine is addictive, so minimum age laws of 18 for sales should be introduced.

### SUPPORT SMOKERS SWITCHING

Regulations should reflect the growing acceptance among many health professionals that nicotine products have huge potential to improve public health by helping people to cut down or quit smoking by choosing less risky alternatives.

> www.bat.com/sustainability 7 British American Tobacco

#### Research

# TRANSPARENCY AND WORLD-CLASS SCIENCE

We are committed to exemplary corporate conduct and transparency across the whole business – this includes our research and development.

Being transparent about our science is central to our approach. We publish details of our scientific research programmes on our dedicated website, **www.bat-science.com**, submit the results of studies to peer-reviewed journals, and present widely at leading international conferences and events.

We understand that some people are sceptical about research conducted and funded by the tobacco industry, but we know it's our responsibility to contribute to the science of tobacco harm reduction. We have state-of-the-art R&D facilities and hundreds of scientists covering many different disciplines, and we work in collaboration with external researchers around the world, such as in the USA, Canada, Spain, Germany, China and Russia.

We even actively encourage regulators and other scientists to visit our research facilities in the UK. And now we've also created a video tour which you can view online at **www.bat.com/labtour**.

# £498m

spent on R&D into innovative tobacco and nicotine products in the last three years

# Top 25%

ranking for investment into R&D among other EU companies<sup>6</sup>

100+

peer-reviewed research papers published in the last five years

6 The 2013 EU Industrial R&D Investment Scoreboard, European Commission Joint Research Centre



# Employee view

MARINA TRANI Head of R&D, Nicoventures



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I've worked for over 20 years in scientific research and development for consumer goods companies – but moving into the tobacco industry was a big step. Like many people I had a very cynical view of the industry, so was quite taken aback by the sheer breadth and quality of BAT's scientific research.

I also think its level of openness is pretty much unprecedented for a commercial business. I've certainly never encountered one so willing to open the doors of its labs to anyone interested in visiting!

Working on this entirely new generation of products, like e-cigarettes and innovative nicotine inhalers, I really feel that we're at the forefront of a whole new era of tobacco harm reduction – it's very exciting to be part of it. Never before have we had products that are both consumer-acceptable and less risky. And this is just the beginning – I think we're going to see many more innovations and developments in nicotine products over the next few years.

There's still a lot to learn about these new products, so we're carrying out our own research to better understand what's being delivered to the consumer and the possible effects.

Importantly, we really go out of our way to make sure we're part of the debate around harm reduction – we have a lot of experience and expertise and can make a valuable contribution. I hope that the science will speak for itself and we'll start to see even more support for nicotine products and the contribution they can make to public health. As I said, it really is exciting times."

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# **GET IN TOUCH**

Susan Jones and Verity Lawson British American Tobacco Globe House, 4 Temple Place London WC2R 2PG

sustainability@bat.com

**1**+44 (0)20 7845 1000



Ernst & Young LLP has been engaged by British American Tobacco to provide limited external assurance of this focus report. A full assurance statement, including the scope of work and conclusions, can be found at www.bat.com/assurance.





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