A FOCUS ON HARM REDUCTION

Why it matters

SUSTAINABILITY FOCUS REPORT 2013: How we address the public health impact of our products

A nicotine molecule
What’s inside this report?

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Our Chief Executive on why it matters

Because it’s crucial to the future of our business.
Surely tobacco harm reduction should just be about getting people to quit smoking?

The only way to be certain of avoiding the serious health risks associated with smoking is not to smoke at all. However, despite increasingly strict tobacco control policies, many people continue to smoke. And the World Health Organisation estimates that many more will do so in the future. So realistically the ‘quit or die’ approach to reducing the public health impact of smoking simply isn’t enough.

For adults that choose to continue to smoke, tobacco harm reduction takes a pragmatic approach by offering them the choice of less risky tobacco and nicotine alternatives.

OK, but can a tobacco company really be serious about harm reduction?

We understand that people will be sceptical about our motivations and how seriously we take this. As well as the moral imperative, it makes commercial sense for us to have a sustainable portfolio of products. Clearly, less risky tobacco and nicotine products must form part of that portfolio. And yes, we most definitely have a responsibility to work to reduce the risks of our products. Harm reduction is a crucial part of our future, with huge potential for business growth, while also benefiting public health.

This is not a new area; harm reduction has been a strategic priority for a long time. In fact, it’s so important that we have two Management Board positions dedicated to this area – Dr David O’Reilly as Group Scientific Director and Des Naughton as Managing Director of Next Generation Products. And earlier this year, we welcomed a new independent Non-Executive Director, Dr Richard Tubb, to our Board of Directors. Dr Tubb is a leading public health figure actively involved in the science and policy development of tobacco harm reduction and alternative nicotine products.

These positions put science and alternative nicotine products at the core of our strategy, and further demonstrate our commitment to our consumers and shareholders.

What areas are you concentrating on?

Our approach to harm reduction has two distinct areas: nicotine-based alternatives and reduced-risk tobacco products.

In the nicotine category, we have established a stand-alone business solely dedicated to this area. This brings together our existing Nicoventures business with CN Creative, the e-cigarette company we acquired at the end of last year, into a single business which will continue to operate under the Nicoventures name.

This business has already launched its first e-cigarette in the UK, which will be expanded into further markets in the coming year. And, as well as e-cigarettes, it’s also developing other innovative nicotine inhalation devices. These products represent the first step towards creating a portfolio of nicotine alternatives, to realise the long-term potential of our harm reduction approach and a sustainable future growth for our business.

Our core business continues to be in tobacco and in this area we continue to focus on scientific research and clinical studies into reduced-risk tobacco products.

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So why do you have a separate business for nicotine products?

The rationale for Nicoventures being separate is to ensure focus. We are determined to create a nicotine business with global scale and reach and we want to ensure the management of it is not distracted with competing demands from the tobacco side of our business.

How do we know we can trust you and have faith in your less risky products?

We know there’s still widespread mistrust of the tobacco industry. That’s why it’s so important that the information consumers get about less risky products is based on robust science. We’re working hard at re-building trust through open and frank communication with society and our consumers, as well as transparency about our scientific research. It may take many more years to do this, but we’re in this for the long haul and I think there’s a lot to be optimistic about in the future.

Nicandro Durante

Nicandro Durante, Chief Executive, November 2013
Exploding the myths...

Focusing on the facts

FACT
Nicotine is not added to cigarettes, it occurs naturally in the tobacco leaf and is also found, albeit at significantly lower levels, in other plants, such as tomatoes, potatoes and aubergines (eggplant).

FACT
Scientists widely agree that it’s not nicotine but in fact the toxicants in tobacco and tobacco smoke that cause the overwhelming majority of smoking-related diseases.

FACT
The World Health Organisation’s International Agency for Research on Cancer has not identified nicotine as a cause of cancer1.

At the core of our business strategy

Our approach to harm reduction

It’s simple; we want to reduce the public health impact of our products. So, harm reduction continues to be at the core of our business strategy. But as consumer preferences vary widely, there’s no one ‘Holy Grail’ product. We’re working hard at making a range of less risky products available by focusing on two key areas:

• Developing nicotine-based alternatives, including e-cigarettes and other inhaled nicotine devices; and

• Scientific research into reduced-risk tobacco products, including reduced toxicant cigarettes and innovative next generation tobacco products.

We’re seeking widespread support for tobacco harm reduction through our engagement and work with scientists and public health professionals. We’re also asking for regulatory changes that will support the commercialisation of reduced-risk, scientifically assessed products.

Weighing up the evidence

It has been determined in public health reports over many years that exposure to nicotine in itself is not a significant risk factor in the development of smoking-related diseases.

The UK Royal College of Physicians states that “medicinal nicotine is a very safe drug”. And the UK Medicines and Healthcare products Regulatory Agency states that “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”.

A pragmatic approach

Tobacco control policy around the world focuses on urging people not to start smoking, or to quit. Yet many adults continue to smoke, and the World Health Organisation estimates that, as the global population increases, so too will the number of smokers. If this is the case, then the pragmatic approach is to offer them less risky alternatives.

1 Harm reduction in nicotine addiction, a report by the Tobacco Advisory Group of the UK Royal College of Physicians, 2007.
Do all products have the same level of risk?

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Exposure to Toxicants</th>
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<tr>
<td>Conventional Cigarettes</td>
<td>HIGH</td>
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<td>Reduced Toxicant Cigarettes</td>
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<td>Heat-not-Burn Cigarette-Like Devices</td>
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<td>Low-toxicant Smokeless Tobacco</td>
<td>LOW</td>
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<td>Nicotine Products</td>
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Innovative nicotine products

Q&A with Des Naughton
Managing Director of Next Generation Products

Q
Aren’t nicotine products just as bad for you as cigarettes?

Q
So how does this fit into your strategy?

Q
So where do you see this category going?
The potential of e-cigarettes for improving public health

E-cigarettes deliver nicotine without smoke toxicants. Consumer research suggests that, due to being closer to the experience of smoking tobacco, they are the first product with the potential to encourage meaningful numbers of smokers to reduce or stop smoking conventional cigarettes. They could therefore play a significant role in helping to reduce the public health impact of tobacco use.

We think that further product development can build on the success of e-cigarettes, achieving greater public health benefits and providing us with a commercial opportunity.

When manufactured to appropriate quality and safety standards, e-cigarettes are substantially less risky than smoking tobacco. However, no product is free from risk.

Nicotine is addictive and can be dangerous if ingested in concentrations much higher than found in cigarette smoke or e-cigarette vapour. Therefore, our e-cigarettes packs, inserts and e-liquid refills have appropriate warnings, are sold in child-proof containers, and are clearly labelled as being for those aged 18 and over. Our marketing of e-cigarettes is aimed at adult smokers only.

Questions are also asked about the possible long-term effects of inhaling substances found in e-liquids, such as glycerol and propylene glycol. Although these ingredients are commonly approved for use in food and medicines, we believe that more research is needed in relation to their inhalation and so we are planning our own studies in this area.

Certain members of the public health community are concerned that e-cigarettes could act as a ‘gateway’ into smoking, particularly for young people. So far there is little evidence to suggest this is the case. Studies in the UK and United States show that 0.5% and 0.8% of adults who had never smoked reported having ever tried an e-cigarette.

Other nicotine inhalation products

As well as e-cigarettes, our Nicoventures business is also focusing on the development of other innovative nicotine inhalation devices. Most of the current nicotine inhalation products on the market are categorised as ‘nicotine replacement therapy’ (NRT) and sold as aids to help people quit smoking. But we think this approach positions smokers as patients. Research shows that smokers don’t perceive themselves as having a disease and we don’t think these NRT products meet their needs.

The UK Department of Health has expressed its interest in encouraging manufacturers “to develop new types of nicotine products that are more affordable and that have increased acceptability for use in the longer term”.

We think we’re up to meeting this challenge and so Nicoventures is working on bringing innovative inhaled nicotine products to market that appeal to smokers as people not patients.

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E-cigarette

A typical e-cigarette consists of three main components: a battery, a heating element and a cartridge containing water, nicotine and other ingredients, including glycerol or propylene glycol, known as ‘e-liquid’. When a user inhales on the device, a sensor detects air flow and the e-liquid is heated so that it turns into vapour, which delivers nicotine to the user. What looks like exhaled smoke is largely odourless vapour.
Q

Do you think nicotine products should be regulated?

A

with Kingsley Wheaton

Group Corporate and Regulatory Affairs Director

Q

So how can you be sure your products meet quality and safety standards?
‘Safer’ tobacco products: the research

Scientific research

Globally, cigarettes are by far the most popular form of tobacco use – not only because of the way they offer nicotine (quickly and with control by the smoker) but also because of taste and the rituals surrounding smoking. Producing less risky products that smokers actually want to switch to is challenging.

Evidence tells us that certain low-toxicant smokeless tobacco products, such as Swedish-style ‘snus’, come with substantially lower risks than cigarette smoking. The wide use of snus among Swedish men is seen as an important reason why Sweden has the lowest rate of male smoking-related diseases of any comparable developed nation. However, snus is currently banned from sale in some parts of the world and, outside of countries that have a history of using oral tobacco, smokers generally don’t like using it in preference to cigarettes.

Yes, alternative nicotine products have great promise, but it’s also really important to look for other ways of reducing the risks of conventional tobacco products.

Why is smoking so harmful?

- Conventional cigarettes are made up almost entirely of tobacco, which when burned produces smoke.
- Exposure to toxicants, by inhaling the smoke, causes the overwhelming majority of smoking-related diseases.
- Tobacco is a plant and burning it, like burning any plant material, turns thousands of plant-based compounds into thousands of other compounds, some of which are toxic.
- The cumulative effect of exposure to these toxicants leads to the onset of smoking-related diseases, so people who smoke more cigarettes a day, over a long period, face a greater risk of developing a smoking-related disease.

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Reduced toxicant cigarettes

We’ve developed new technologies to reduce some of the toxicants in the smoke, which we’re testing in prototype cigarettes. We’re researching their potential to reduce exposure to toxicants and, ultimately, health risks.

A lot of this research is lab-based. It includes tests involving the development of *in vitro* models of disease and computational toxicological models to determine which are the most important toxicants, and how much they would need to be reduced to lessen health risks. This research supports our approach, but the key evidence of the possible exposure and risk reduction comes from clinical studies of groups of smokers.

Our first clinical study of this kind showed that smokers who switched to the reduced toxicant prototype cigarettes had less exposure to certain smoke toxicants than people smoking conventional cigarettes.

This is a good first step. But we did not determine whether the reduced exposure will reduce risk. In 2012, we completed the clinical phase of a longer study to measure biomarkers of biological effect that could indicate changes in the body relating to diseases. Initial results of the study have been presented to the joint meeting of the US Food and Drug Administration’s Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee. We will be submitting the full findings to peer-reviewed journals at the end of 2013.

Other innovative tobacco products

We are also exploring the development of other innovative tobacco products, such as ‘heat-not-burn’ cigarette-like devices. These gently heat the tobacco, instead of burning it, which potentially exposes users to lower levels of toxicants.
Q&A with Dr David O’Reilly
Group Scientific Director

Q
Will there ever be a ‘safer’ cigarette?

Q
Can scientific research by tobacco companies ever really be credible?

Q
So how important is the science behind harm reduction?
The bigger picture

Developing reduced-risk tobacco products will be less impactful if information about the different risk profiles cannot be communicated to consumers so they can make informed choices. To do this there needs to be an agreed science-based regulatory framework for evaluating these products. The challenge is to build a sufficient weight of scientific evidence to base such regulation and consumer information on.

To date, the only regulator to rise to the challenge is the US Food and Drug Administration (FDA), which has authority in the United States to regulate tobacco products, including evaluating submissions on candidate ‘modified risk tobacco products’.

In 2012, a funding initiative by the inter-agency partnership between the FDA and the US National Institutes of Health was announced, focusing on finding scientific evidence to support regulation, including the characterisation of modified risk tobacco products. We think this kind of collaboration and inclusive approach is a really positive step and we’re working with some of our research partners in submitting applications.

"What do external experts think?"
To achieve our aim of being able to offer a range of less risky tobacco and nicotine alternatives that consumers actually want to use, we still need to undertake a great deal more research and development – which we’re very much committed to for the long term.

In the short term, our Nicoventures business will continue to build a portfolio of next generation nicotine products, including further development of e-cigarettes and the development of other innovative nicotine inhalation products.

More collaboration between the tobacco industry, academia and tobacco research centres is also key to establishing an evidence-based regulatory framework to assess new products.

Ultimately, consumers need to be able to make an informed choice about different products based on their risk profile. So, as well as developing new products, we have a role to contribute to the robust science that will help provide them with that information.

So, what’s next?

Dr Delon Human
Author of *Wise Nicotine*, President and CEO of NicoLife, a global health advisory and consulting practice on tobacco harm reduction; and former Secretary-General and CEO of the World Medical Association

Dr Richard Tubb
Independent Non-Executive Director, Board of British American Tobacco p.l.c.

1 NicoLife has provided consultancy services to BAT on our approach to harm reduction.
Independent assurance

Independent Assurance Statement to British American Tobacco Management

The British American Tobacco p.l.c. A Focus on Harm Reduction Report 2013 (the Report) has been prepared by the management of British American Tobacco (BAT), which is responsible for the collection and presentation of the information within it. Our responsibility, in accordance with management's instructions, is to carry out a ‘limited level’ assurance engagement on the Report. We do not accept or assume any responsibility for any other purpose or to any other person or organisation. Any reliance any such third party may place on the Report is entirely at its own risk.

What we did to form our conclusions

Our assurance engagement has been planned and performed in accordance with ISAE3000¹. The criteria used to form our conclusions are defined as follows:

Materiality
Whether disclosures in the Report address key stakeholder issues regarding harm reduction raised through our review of recent media and Board CSR Committee papers.

Accuracy
Whether there is supporting information for data and claims made regarding BAT’s activities on harm reduction.

In order to form our conclusions we undertook the steps outlined below:

1. Compared the coverage of material issues within the Report against the key issues raised in our review of external media and issues raised in the Board CSR Committee papers.

2. Interviewed three managers at BAT regarding the activities undertaken as part of the harm reduction agenda.

3. Reviewed information or explanations about selected data and claims made regarding BAT’s harm reduction activities.

Level of assurance

Our evidence gathering procedures were designed to obtain a limited level of assurance (as set out in ISAE3000) on which to base our conclusions. The extent of evidence gathering procedures performed is less than that of a reasonable assurance engagement (such as a financial audit) and therefore a lower level of assurance is provided.

The limitations of our review

We have interviewed management at Group-level. We have not visited BAT’s research and development facilities.

¹ ISAE3000 – International Federation of the Accountants' International Standard for Assurance Engagements Other Than Audits or Reviews of Historical Financial Information.
Our conclusions

Based on the scope of our review our conclusions are outlined below:

Materiality
Has British American Tobacco addressed the material issues?

With the exception of the issue listed below, we are not aware of any material aspects raised in our review of media and Board CSR Committee papers which have been excluded from the Report.

- We consider that BAT should have covered the issues concerning the marketing of nicotine inhalation devices, including e-cigarettes, and their corporate position in more detail in the Report.

Accuracy
How plausible are the statements and claims within the Report?

We have reviewed information or explanations on the selected statements on BAT’s harm reduction activities presented in the Report and we are not aware of any misstatements in the assertions made.

Our independence

Ernst & Young LLP has provided independent assurance services in relation to BAT’s sustainability reporting for six years. We have provided no other services relating to BAT’s approach to sustainability reporting.

Our assurance team

Our assurance team has been drawn from our global environment and sustainability network, which undertakes engagements similar to this with a number of significant UK and international businesses.

Ernst & Young LLP

London
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About this report
This is a report by British American Tobacco p.l.c. Associate companies are excluded. References to ‘British American Tobacco’, ‘BAT’, ‘we’, ‘us’ and ‘our’ when denoting opinion refer to British American Tobacco p.l.c. (the Company), and when denoting tobacco business activity refer to Group operating companies, collectively or individually as the case may be. This report contains forward-looking statements that are subject to risk factors associated with, among other things, the economic and business circumstances occurring in the countries in which the Group operates. It is believed that the expectations reflected in these statements are reasonable, but they may be affected by a wide range of variables that could cause actual results to differ materially from those currently anticipated. Designed and produced by Flag. Photography by David Hares.