Department of Health & Social Care

The Government Response to the Science and Technology Committee's Seventh Report of the Session 2017-19 on E-cigarettes

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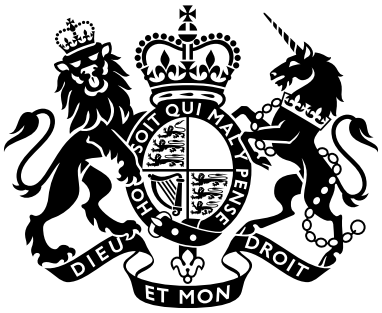

The Government Response to the Science and Technology Committee's Seventh Report of the Session 2017-19 on E-cigarettes

Presented to Parliament

by the Secretary of State for Health and Social Care

By Command of Her Majesty

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Introduction

This Command Paper sets out the UK Government's response to the Science and Technology Committee's Seventh Report of the Session 2017-19 on E-cigarettes.

The Government welcomes the Committee's Report and the important contribution it makes to the wider debate on e-cigarettes.

The context for policy on e-cigarettes is the continuing tobacco epidemic. Smoking causes over 78,000 deaths a year and is the leading cause of preventable illness and premature death in England. The financial burden that this puts on the National Health Service (NHS) in England, and other public services is huge, but the costs go far beyond the financial: a regular, long-term smoker loses an average of 10 years of their life due to their habit. Great progress has been made over the past decade in reducing adult smoking prevalence to 14.9%, the lowest rate on record, although there remain considerable inequalities: some poorer communities remain blighted by tobacco. However, the Government recognises we cannot be complacent and in its Tobacco Control Plan for England, published in July 2017, set out a series of ambitions to reduce prevalence still further, en route to the eventual goal of a smoke free generation.[1] The plan also made a commitment to promote a proportionate approach to harm reduction.

The Government believes in proportionate regulation of e-cigarettes, recognising that they are not risk-free. Through the European Union Tobacco Products Directive 2014/40/EU (TPD), transposed into UK law by the UK Tobacco and Related Products Regulations 2016 (TRPR), we have introduced measures to regulate e-cigarettes to reduce the risk of harm to children, protect against any risk of renormalisation of tobacco use, provide assurance on relative safety for users, and give businesses legal certainty. This has enabled the United Kingdom to implement appropriate standards for products whilst allowing smokers to move to e-cigarettes should they wish.

The Government has consistently highlighted that quitting smoking and nicotine use completely is the best way to improve health. E-cigarettes are not risk free. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco, and can help smokers to quit, particularly when combined with stop smoking services. Some two and a half million people in England now use e-cigarettes, many using them to quit smoking for good.

The Government does take concerns about e-cigarettes seriously. That is why in the Tobacco Control Plan for England it committed to monitor the impact of regulation and policy on e-cigarettes and novel tobacco products (including evidence on safety, uptake, the health impact and effectiveness of these products as smoking cessation aids) to inform future policy. Public Health England (PHE) will continue to update its evidence base on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022, with the next review expected to be available in early 2019.

[1] "smokefree generation" is defined as reducing adult smoking prevalence to below 5%

Those reviews will support the assessment of tobacco and related products legislation to which the Government is committed once we have left the European Union (EU). In doing so the UK Government will seek to explore where regulation can be modified, whilst still offering the highest possible protection of health. As health is devolved, we will continue to engage with officials in the devolved administrations as we move forward.

Reducing Harm

Recommendation 1

To help fill remaining gaps in the evidence on the relative risks of e-cigarettes and heat-not-burn products, the Government should maintain its planned annual 'evidence review' on e-cigarettes and extend it to also cover heat-not-burn products. It should support a long-term research programme, to be overseen by Public Health England and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment, to ensure that health-related evidence is not dependent solely on the tobacco industry or the manufacturers of e-cigarettes. That PHE/COT research should include examining health risks arising from the flavourings added to e-cigarettes. The Government should report each year on the state of research in its Tobacco Control Plan, and establish an online hub for making the detailed evidence readily available to the public and to health professionals.

The Government accepts this recommendation. PHE will continue to review the evidence on e-cigarettes on an annual basis for the rest of this Parliament, and will examine evidence on heated tobacco products as new evidence emerges. PHE will provide smokers and the public with clear, evidence based and accurate information on the relative harm of nicotine, e-cigarettes, other nicotine delivery systems and smoked tobacco, to enable informed decision-making. This also includes monitoring the evidence annually on the appeal of e-cigarettes to young people.

The Government is firmly committed to more research in this area. As outlined in the Department of Health and Social Care's written response to the Committee's inquiry the Department has provided funding for e-cigarette research. Examples of work in progress include:

- A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within UK stop smoking services
- Impacts of e-cigarette regulation via the EU Tobacco Products Directive on young people's use of e-cigarettes: a natural experiment
- Helping pregnant smokers quit: Multi-centre randomised control trial of electronic cigarettes as opposed to usual care.

The Department has engaged with the UK E-Cigarette Research Forum, an initiative developed by Cancer Research UK in partnership with PHE and the UK Centre for Tobacco and Alcohol Studies, to identify potential areas of future research. The current programme of work led by Cancer Research UK includes the following research topics: cessation, safety/health impact, marketing and tobacco industry, regulation, hard to reach groups, perceptions, population trends and behaviour.

The Government has already commissioned the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) a committee of independent experts that provides advice to Government on matters concerning the toxicity of chemicals in food, consumer products and the environment, to consider areas of research on potential harms from e-cigarettes. The COT will be supported in this as required by the Committee on Mutagenicity of Chemicals in Food, Consumer

Products and the Environment (COM) and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), in matters relating to their specialist areas of expertise.

Last year the COT considered several papers on the characteristics of e-cigarette aerosols. To date during this current financial year, the COT has considered papers on the toxicity of propylene glycol and glycerol, the toxicological and epidemiological evaluations of e-cigarette aerosol for both nicotine and non-nicotine containing systems, and a preliminary overview of nicotine toxicity. In addition, COM and COC have reviewed the available evidence on genotoxicity and carcinogenicity respectively. During the rest of the year, the COT will do further work on the impact of nicotine on e-cigarette aerosols and on the toxicity of flavourings. Once the programme of work is complete a COT statement on the toxicological risks of e-cigarettes will be prepared.

PHE currently has a toxicological research program examining some specific risks associated with e-cigarettes. This includes work to consider the possible risks from flavourings and additives, biomonitoring of nicotine-derived nitrosamines, and exploration of the physiological and psychological impacts on individuals of switching to e-cigarettes.

In regard to heated tobacco products and understanding their role in harm reduction, the Government asked COT to provide it with an independent assessment to research the toxicological risks of both heat not burn products and compare these to those attributed to conventional cigarettes. The COT published its position on its views on the 12 December 2017. It found that:

- The evidence suggests that heat not burn products still pose a risk to users. There is likely to be a reduction in risk for cigarette smokers who switch to heat not burn products but quitting entirely would be more beneficial.

- People using these products are exposed to between 50 and 90 percent less of the ‘harmful and potentially harmful’ compounds compared with conventional cigarettes. COT was unable to precisely quantify the risk from heat not burn products compared with conventional cigarettes because limited data is available. Nor was COT able to conclude anything concerning the risks of heat not burn products compared to e-cigarettes.

- There is a reduction in risk to bystanders where conventional smokers switch to heat not burn products.

- The risk to the unborn child from women using these products during pregnancy is difficult to quantify and the aim should be to quit entirely.

- Non-smokers should not take up these products because they are not without risk.

PHE’s latest evidence review also has a chapter on research dedicated to these areas and drew similar conclusions to those made by COT.

Both PHE and COT identified shortcomings in the current evidence base: there are no long-term studies as these products are relatively new, and a majority of the research has been carried out by the tobacco industry. The Government will review and consider where there are gaps in evidence for further independent research, and continues to collaborate and share knowledge both in the UK and internationally to help develop the research base and understanding of these products. The UK Government is also represented on the Global Tobacco Regulators' Forum. This brings together a number of countries, as well as the European Union and World Health Organization, to discuss regulatory issues of common interest.

The Government is committed to providing the outputs of research to the public on the risks of e-cigarettes and novel tobacco products. The evidence base on e-cigarettes is widening with more independent research and longer-term use of these products which is helping better inform policy understanding to communicate to the public. The Government will continue to publish all the research it funds through the usual channels on the dedicated www.gov.uk website.

E-cigarettes and Smoking Cessation

Recommendation 2

The Government should review with MHRA and the e-cigarette industry how its systems for approving stop smoking therapies could be streamlined; to be able to respond appropriately should manufacturers put forward a product for licensing.

The Government accepts this recommendation. Below is a brief summary of the process for authorisation, and the steps the Medicines and Healthcare Products Regulatory Agency (MHRA) is already taking to make it easier for companies producing e-cigarettes who wish to pursue the medicinal product route. Essentially, manufacturers can apply for a medicines marketing authorisation from the MHRA as with any other medicinal product, with a view to that product becoming available for clinicians to prescribe. To do so they need to supply a range of data about the product's quality, safety and efficacy. Quality data will include information on its composition, manufacturing process, quality control and evidence that it is stable over its shelf life. Details of the delivery device and its performance are also needed. Safety data will include confirmation that the ingredients are safe when inhaled. Clinical efficacy trials are not needed; assessment of efficacy is based on evidence that adequate blood levels of nicotine are achieved.

To date, two manufacturers have taken this approach. With one, the authorised products have not been commercialised, in the other case the application process has not yet been completed. A small number of other manufacturers have expressed interest in obtaining a licence but are not yet in a position to submit an application.

The Government made a commitment in the Tobacco Control Plan for England to ensure that the system for authorising e-cigarettes as medicinal products is fit for purpose so that a range of safe and effective products can potentially be made available for NHS prescription. Any potential changes proposed would need to be considered in the context of the statutory data requirements for medicines and medical device legislations which must be met for licensing the products. As part of the Tobacco Control Delivery Plan MHRA accordingly agreed to:

- Engage further with companies who have been in contact for scientific/regulatory advice to discuss whether they require further assistance.

- Produce a myth busters document clarifying the route to e-cigarette medicinal licensing.

- Host a meeting with e-cigarette trade associations to explore the views of Small and Medium Enterprises on e-cigarette medicinal licensing and report on progress to the Department of Health and Social Care.

In regard to progress MHRA has followed up with companies individually and in May met the Independent British Vape Trade Association and the UK Vaping Industry Association. The industry has highlighted to the MHRA that their products have a short lifecycle, given the commercial imperative to make frequent changes. As a result frequent data updates to comply with medicines legislation is challenging.

Ultimately, it is a commercial decision for e-cigarette manufacturers to make whether or not to apply for a medicinal licence. Despite the lack of a medicinal approved e-cigarettes, there are around two and a half million e-cigarette users in England alone, which suggests that growth of the e-cigarette market has not been hindered due to e-cigarettes not being available on prescription. They are widely available and accessed, and are sold in pharmacies. We continue to promote the message that people have found the use of e-cigarettes helpful to stop smoking, for example in the PHE Stoptober campaigns. The National Institute for Health and Care Excellence (NICE) have also issued clinical guidelines for health professionals on messages which they can use when discussing stopping smoking with patients. NICE has highlighted that the evidence suggests e-cigarettes are less harmful to health than smoking, and that many people have found them helpful to quit smoking cigarettes. NICE notes that e-cigarettes are not risk free and evidence on the long-term health impact is still developing [2].

[2] NICE guideline NG92, published March 2018
https://www.nice.org.uk/guidance/ng92/chapter/Recommendations#advice-on-ecigarettes

Recommendation 3

NHS England should as a matter of urgency ensure that there is a position created for a dedicated person within the NHS England responsible for implementing the Government's Tobacco Control Plan.

The Government broadly accepts this recommendation. NHS England is aware of its responsibilities within the Tobacco Control Plan. The Department of Health and Social Care has worked with NHS England to produce the Tobacco Control Plan Delivery Plan 2017-2022. The Delivery Plan will be closely monitored to ensure that the Government's ambitions can be met.

Recommendation 4

NHS England should set a clear central NHS policy on e-cigarettes in mental health facilities which establishes a default of allowing e-cigarette use by patients unless an NHS trust can show reasons for not doing so which are demonstrably evidence-based. NHS England should issue e-cigarette guidance to all NHS mental health trusts to ensure that they understand the physical and mental health benefits for their patients.

The Government accepts this recommendation and stands by the position that tobacco smoking in NHS facilities is not appropriate.

The NHS will be guided by Public Health England's recommendation that using an e-cigarette regularly is much less harmful than tobacco smoking. NHS England will provide guidance to mental health trusts that sets out that existing vapers should be permitted to use e-cigarettes as part of smoking cessation programmes, and that existing tobacco smokers should be supported to stop smoking through smoking cessation programmes, which may include switching to e-cigarettes use whilst in inpatient settings.

Regulation

Recommendation 5

The Government, together with the ASA and the MHRA, should review all these regulatory anomalies and, to the extent that EU directives do not present barriers, publish a plan for addressing these in the next annual Tobacco Control Plan.

The Government broadly accepts this recommendation and is committed to reviewing tobacco legislation as and when appropriate. While the UK Government is a member of the EU it will continue to comply with the requirements of the EU's Tobacco Products Directive 2014/40/EU (TPD), transposed into UK legislation through the Tobacco and Related Products Regulation 2016 (TRPR). The Government has made a commitment to review the TRPR by May 2021 to consider its regulatory impact. In addition, as announced in the Tobacco Control Plan the Government will review where the UK's exit from the EU offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. The Government will explore those areas identified by the Committee, such as the 20mg/ml maximum nicotine refill limit, a size restriction of 2ml on the tank, a block on advertising e-cigarettes' relative harm-reduction potential and the notification scheme for e-cigarette ingredients.

Although there are advertising restrictions on vaping, they are less stringent than those which apply to tobacco products. The Government will of course consider when it reviews the legislation whether these restrictions fully reflect the differing risks of harm arising from tobacco products and e-cigarettes. We would note to the Committee that the Government has issued a direction to Ofcom clarifying that under the current code on television and radio advertising it is permissible for public health campaigns to promote the generic use of e-cigarettes for quitting smoking. This direction will support campaigns such as Stoptober which have promoted the use of e-cigarettes for quitting.

While recognising the different regulatory environment in the United States, the Government notes with concern the increasing evidence that e-cigarettes are causing what the US Food and Drug Administration (FDA) has described as "epidemic" levels of teenage vaping, with substantial increases in the past year, despite federal regulations prohibiting sales to under 18-year olds[3]. Regular use of e-cigarettes by young people in the UK remains very low, but we will continue to track teenage use of e-cigarettes in this country, and will not hesitate to consider further regulatory action, in the event that the data suggests they are causing an increase in youth nicotine consumption.

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3 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625917.htm?utm_campaign=111518_PR_New%20federal%20findings%20show%20dramatic%20increase%20in%20youth%20e-cigarette%20use&utm_medium=email&utm_source=Eloqua

The Committee has suggested that inserts could be included within cigarette packets to refer to e-cigarettes as an alternative to smoking. Such inserts are banned under the Standardised Packaging of Tobacco Products Regulations 2015. However, in the absence of such inserts the outside front packaging of tobacco products provides users with a dedicated website to receive information on various means of stopping smoking, including the use of e-cigarettes.

The Government is committed to reviewing the standardised packaging legislation by May 2021. At that point the Government will consider whether the banning of pack inserts is having a positive or negative impact on health.

In general, the Government is committed to a proportionate system of regulation, one which protects youth from access to harmful products and which discourages non-smokers from starting smoking. In taking forward the review of the legislation the Government will remain focused on protecting the health of the public.

Recommendation 6

The level of taxation on smoking-related products should directly correspond to the health risks that they present, to encourage less harmful consumption. Applying that logic, e-cigarettes should remain the least-taxed and conventional cigarettes the most, with heat-not-burn products falling between the two.

The Government accepts this recommendation, which reflects current practice. E-cigarettes are currently taxed as a consumer product with the VAT rate being 20%. With tobacco products being taxed at a higher rate there is already a clear financial benefit for switching to e-cigarettes.

Heat not burn products are regulated under the TRPR as novel tobacco products and for taxation purposes are classed, on an interim basis, as other smoking tobacco products. This level of excise duty is the lowest available for tobacco. The Government has committed to introducing a dedicated category of tobacco for heating for taxation purposes. As outlined earlier, there is limited evidence available about the relative harms to health from use of heat not burn products. The Committee on Toxicity concluded that they were less harmful than cigarettes, but more harmful than e-cigarettes. We expect the taxation system to reflect this, whilst noting that where tobacco is taxed on a weight basis heat not burn products generally have an advantage as they contain comparatively less tobacco.

The European Commission has launched a review of the existing rules for excise duty on tobacco and tobacco products. As part of this review it intends to collect more evidence on vaping products. The UK successfully pushed that this analysis should include public health impacts as well as tax issues and will continue to make this case. Any proposals arising from this review would require the unanimous support of all Member States.

Recommendation 7

The Government should conduct a review of regulations on e-cigarettes and novel tobacco products which are currently applied under EU legislation, to identify scope for change post-Brexit, including an evidence-based review of the case for discontinuing the ban on 'snus' oral tobacco. This should be part of a wider shift to a more risk-proportionate regulatory environment; where regulations, advertising rules and tax/duties reflect the evidence on the relative harms of the various e-cigarette and tobacco products available. While an evidence-based approach is important, it also may help bring forward the behaviours that we want as a society—less smoking, and greater use and acceptance of e-cigarettes and novel tobacco products if that serves to reduce smoking rates.

The Government accepts this recommendation. We have committed in the Tobacco Control Plan to review where the UK's exit from the European Union offers us opportunities to re-appraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where current EU regulations limit our ability to deal with tobacco. The Government's goal will remain to achieve a proportionate approach to managing risk, one which protects the young and non-smokers, whilst giving smokers access to products which will reduce harm. As part of this the Government will consider reviewing the position on snus and whether the introduction of this product onto the UK market would promote that kind of proportionate harm reduction approach.

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