Written evidence submitted by the Department of Health (England)
(ECG0030)

Executive Summary

- The Department of Health welcomes the Science and Technology Committee’s E-cigarette Inquiry, which will provide an independent view on this important subject.

- Progress has been made over the past decade in reducing smoking prevalence. This should be welcomed, but we cannot be complacent: there are still 7.3 million smokers in England. Two hundred people die every day due to smoking and it is still the biggest preventable killer in our country. The financial burden that this puts on the NHS in England, and other public services, is obviously 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.

- In England the use of e-cigarettes has increased from 1.6m users in 2014 to around 2.4 million in 2016. That represents huge growth in the past two years. E-cigarettes have by far become the most popular smoking quitting aid in England, and the evidence is that they are not a gateway into smoking.

- The best way for smokers to improve their health is to quit smoking and nicotine use completely. However, the evidence is increasingly clear that e-cigarettes are significantly less harmful to health than smoking tobacco and most importantly that they can help smokers to quit, particularly when combined with stop smoking services. As outlined in the Government’s new Tobacco Control Plan we are committed to supporting consumers in stopping smoking and adopting the use of less harmful nicotine products.

- Whilst recognizing their potential benefits in terms of reducing harms to smokers the Government takes concerns about e-cigarettes seriously. As outlined in the Tobacco Control Plan the Department of Health will monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England (including evidence on safety, uptake, the health impact and effectiveness of these products as smoking cessation aids) to inform our future policy. Public Health England will also update its evidence base on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022.

- The UK Government’s approach towards e-cigarettes is therefore sensible and pragmatic. There are some indications that other countries are taking similar approaches, for example, New Zealand.

Introduction

1. This is the Department of Health’s (DH) response to the Committee’s request for evidence. The Medicines and Healthcare Products Regulatory Agency (MHRA), Public Health England (PHE) and the National Institute for Health and Clinical Excellence (NICE) will also respond to this inquiry.

2. The law concerning e-cigarettes is governed by the Tobacco Products Directive (TPD) 2014/14/EU, implemented in the UK by The UK Tobacco and Related Products Regulations 2016 (TRPR). Part 6 of the TRPR sets out the requirements for e-cigarettes and refill containers. MHRA is the competent authority for the notification scheme for e-cigarettes and refill containers in the UK.
3. The DH is responsible for policy on tobacco control, including on e-cigarettes. In doing so, it is assisted by PHE, which provides the evidence base, and MHRA as regulator. DH believes the current regulatory framework provides minimum standards for safety and quality of all e-cigarettes, ensures information is provided to consumers so that they can make informed choices, and most of all creates an environment that protects children from beginning to use these products.

4. The DH takes concerns about e-cigarettes seriously, and, as outlined in the Tobacco Control Plan 2017, the DH will monitor the impact of regulation and policy on e-cigarettes and novel tobacco products in England, (including evidence on safety, uptake, the health impact and effectiveness of these products as smoking cessation aids), to inform our actions and regulate their use. PHE will also update its evidence report on e-cigarettes and other novel nicotine delivery systems annually until the end of the Parliament in 2022.

Health

5. The DH has been clear 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.

6. The emerging evidence on the relative harm of nicotine containing products has been set out in a number of publications. These include: Tobacco Harm Reduction (Royal College of Physicians, 2007); Nicotine without Smoke (Royal College of Physicians, 2016); Beyond Smoking Kills (Action on Smoking on Health (ASH) 2008); Smoking Still Kills (ASH, 2016); NICE Harm Reduction Guidelines (2013), and British Psychological Society Changing Behaviour: Electronic cigarettes (2017). Charities such as Cancer Research UK have also published advice around the benefits to public health if smokers move to using e-cigarettes.

7. To support further independent research and collaboration, the UK E-Cigarette Research Forum (UKECRF) is an initiative developed by Cancer Research UK in partnership with PHE and the UK Centre for Tobacco and Alcohol Studies (UKCTAS). The Forum brings together policy-makers, researchers, practitioners and the NGO community to discuss the emerging evidence and knowledge gaps about e-cigarettes. The group also seeks to identify research priorities, generate ideas for new research projects and enhance collaboration between forum participants. The DH has been asked by the UKECRF forum to contribute suggestions for further areas of e-cigarette research to help develop improvements in policy to achieve the Tobacco Control Plan aims. The Department’s response is presented in Annex A. In addition, Annex B also provides a list of Government funded e-cigarettes research, both present and past.

8. The Government acknowledges that e-cigarettes are still a relatively new product and thus we do not have long-term epidemiological evidence on harms. The DH is committed to receive annual evidence review from PHE on the impact and harms from e-cigarettes, with the next review expected to be available in early 2018. The review will cover the latest evidence on adult and youth prevalence, safety, effectiveness for quitting and perceptions of harmfulness, addictiveness of nicotine and a section on heat-not-burn tobacco products.
9. There are often misleading media stories about e-cigarettes harms and these stories have the potential to confuse the public. In an attempt to mitigate this and provide clear understanding a joint statement was issued by PHE and other UK public health organisations in July 2016\(^1\) stating “We all agree that e-cigarettes are significantly less harmful than smoking. One in two lifelong smokers dies from their addiction. All the evidence suggests that the health risks posed by e-cigarettes are relatively small by comparison but we must continue to study the long-term effects.”

10. Reflecting this position, the Government committed PHE, through the Tobacco Control Plan, to include messages about the relative safety of e-cigarettes in their quit smoking campaigns. PHE’s recent Stoptober campaign, for the first time, highlights e-cigarettes among the array of tools that smokers can use to improve their chances of quitting successfully.

11. PHE are already preparing their New Year quitting campaign in which they will reprise these messages. It is through this consistent messaging that we can hope to reverse the harmful, mistaken – and increasingly widespread – belief that vaping is no safer than smoking.

12. There are specific groups such as pregnant women and persons with mental illness targeted in the Tobacco Control Plan to reduce their smoking prevalence. We believe further research is required to understand the use of e-cigarettes with such groups to aid smoking cessation. We have been made aware that for patients with a mental illness some public health and the NHS bodies are taking measures to offer advice and support to encourage those who smoke to move to alternative products as e-cigarettes, with a goal of moving towards none nicotine dependence in the future.

13. In terms of the potential for e-cigarettes to be an aid to stop smoking tool, it has been estimated that e-cigarettes contribute around 16,000 to 22,000 successful long term quitters per year who would not otherwise have quit had they used nicotine replacement therapy (NRT) bought in a shop, or will power alone\(^2\).

14. The DH through the National Institute for Health Research (NIHR) funded an update on a Cochrane review of the electronic cigarettes for smoking cessation and the results were published in September 2016\(^3\). The conclusions of this updated review are unchanged since the last review was published two years ago: electronic cigarettes may help smokers stop their smoking, and the included studies did not find any serious side effects associated with their use for up to two years. The National Centre for Smoking Cessation and Training (NCSCT) also provided the Electronic cigarettes: A briefing for stop smoking services, January 2016 to assist stop smoking services to support people who want to use e-cigarettes to help them quit smoking.

15. In regards to e-cigarettes in youth and renormalising smoking, there is no great evidence in the UK that vaping is leading young people to smoke. There is some evidence that some young people experiment with e-cigarettes, but that regular e-cigarette use is

\(^2\) BMJ 2016;352:i1243
\(^3\) http://www.cochranelibrary.com/enhanced/exportCitation/doi/10.1002/14651858.CD010216.pub3
confined almost entirely to young people who have smoked⁴. To ensure that remains the
case, we have implemented domestic age-of-sale legislation that prevents the sale of e-
cigarettes to under-18s and we have prohibited the advertising and promotion of e-
cigarettes in the major media streams, including TV, radio, newspapers and the internet.
By and large, the banned media streams are those with the largest reach, and by
controlling them we have significantly reduced children’s exposure to marketing and
images of those products. We continue to review the data on e-cigarette use to monitor
the situation.

Regulation

16. The DH believes the e-cigarette regulatory framework is proportionate. The EU TPD has
enabled us, through the TRPR 2016, to introduce measures to regulate e-cigarettes to
reduce the risk of harm to children and protect against any risk of renormalisation of
tobacco use, provide assurance on relative safety for users, and provide legal certainty
for businesses. This has enabled the UK to implement standards and consistency. There
are a few exceptions in terms of UK domestic law and it is right for each UK country to
decide on those matters. For example, in Scotland there are powers to introduce
domestic legislation banning domestic advertising of e-cigarettes. This is a matter for the
Scottish Parliament.

17. As set out 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 look to identify where it can
sensibly deregulate without harming public health or where EU regulations limit our
ability to deal with tobacco. In particular, the Government will assess recent legislation
such as the TPD, including as it applies to e-cigarettes, and consider where the UK’s exit
provides opportunity to alter the legislative provisions to provide for improved health
outcomes within the UK context.

18. The Government also has a statutory duty to conduct an implementation review of the
Tobacco and Related Products Regulations 2016, by the end of May 2021 to assess its
impact.

19. With regards to advertising and marketing, the Government considers the current
restrictions to be fair. Young people are protected from the re-normalisation of smoking
and, as noted above, are not taking up vaping as a gateway to smoking. The increase in
the number of e-cigarette users amongst adult smokers is evidence that the vaping
industry has not been prevented from expansion.

20. In terms of the device for e-cigarettes, the TPD is clear that only parts of an e-cigarette
device containing nicotine are captured under this Directive. Outside of this there are
other rules and regulations that devices have to comply with to ensure they are safe for
the UK market. Organisations such as Electronic Cigarette Industry Trade Association
(ECITA)⁵ provide advice on such regulations. In addition, there are international groups
working on the safety of e-cigarettes, for example the European Committee for
Standardization (CEN), has a technical committee (CEN/TC 437 Electronic cigarettes
and e-liquids).

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⁴ NHS Digital, Smoking, Drinking and Drug Use among Young People in England 2016
⁵ http://ecita.org.uk
21. The Government believes that the current regulatory framework provides sufficient safeguards around safety of products. However, we are not complacent and welcome further work to identify if there are gaps on device safety to protect consumers. This will be covered as part of the wider impact of the TRPR 2016 review.

Finance

22. Use of e-cigarettes has increased from 1.6m users in 2014 to around 2.4 million in 2016 in England\(^6\). That represents huge growth over the past two years and it is estimated that the industry in the UK is worth in the region of £1 billion.\(^7\) The industry started out from small independent non-tobacco industry organisations, with the intent to design solutions for people to have the benefits of nicotine without the harms from smoking. The DH meets regularly with the Independent British Vape Trade Association to discuss industry concerns and wider regulatory matters. DH does not meet companies which are owned by tobacco companies, as this would put us in breach of our obligations under the Framework Convention on Tobacco Control (FCTC).

23. The implementation of the TPD into the UK is very recent and there may be impacts on UK business as a result of moving to a new regulatory framework. It is too early to tell at the moment if there are negative impacts on the industry and DH will keep this under review as part of our commitment set out in the previous section on regulation.

24. There are potential cost advantages both to the NHS, wider public services, business as well as individual health and lifestyle for people moving from smoking to vaping. From a purely financial point of view, irrespective of long-term health benefits, there a significant savings to smokers from moving to e-cigarettes, given they are exempt from tobacco excise duty. Cancer Research UK estimates that an average smoker, spending £400 every 3 months on their habit, would reduce their spending to £190 every 3 months if they switched to vaping.\(^8\)

25. If vaping is used successfully as an aid to quit, then smokers are likely to see significant long-term savings, especially if they eventually stop vaping as well. The costs are less certain for dual users but any reduction in tobacco use is likely to save them money. Besides the 51.6% of vapers who said stopping smoking was their primary motivation for vaping, a further 7.2% cited cost savings specifically\(^9\).

26. The potential financial impacts of e-cigarettes on the NHS are not yet fully understood, largely because vaping is still relatively new and the health effects may be very long term. The Tobacco Control Plan estimates that the NHS currently spends £2.5bn on smoking-related diseases and PHE assess e-cigarettes to be around 95% less harmful than smoking. Reduced harm may not translate exactly into proportional costs savings, but superficially this implies that vaping, as an alternative to smoking, may contribute to significant savings.

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\(^{6}\) ONS E-cigarette use in England data 2014,15 and16  
\(^{7}\) www.ccigintelligence.com  
\(^{9}\) ONS Adult Smoking Habits 2016.
27. Any improvement in smoking-related health may indirectly increase costs elsewhere in the NHS and care system as people live longer. This, along with fiscal tax impacts, needs to be researched further.

**Novel Tobacco Products**

28. Two heat not burn products have been notified for use on the UK market as novel tobacco products. In comparison to e-cigarettes this market is very new and currently small scale in the UK. We do not know enough about these products and we will continue to adopt a pragmatic approach to regulation, based on the best possible public health evidence.

29. As part of this evidence, the Committee on Toxicity has been asked by the Department of Health to give a view on the potential of heat not burn products to support harm reduction in comparison to conventional smoking. The committee is due to respond later this year.

30. The Government is also analysing the responses to the consultation on the tax treatment of heated tobacco products and will report in due course.

*December 2017*
The Department have been asked by research stakeholders for views on e-cigarettes to support policy and regulatory developments in alignment with the Tobacco Control Plan. In order to prioritise investment, a suggested list of areas of research is outlined below, with further potential areas of research for future consideration.

Suggested priority areas of research:

- Among consumers and bystanders, what effect do maximum nicotine concentrations have on toxicant exposure and (among consumers) patterns of use? We are particularly interested in heavily addicted and socially marginalised smokers.
- Among a) smokers b) vapers and c) non-smoker/non vapers, what are the effect of EC on pack health warnings in terms of their smoking and vaping attitudes and behaviours?
- Among adults and youth, what effect does EC advertising (and advertising prohibition) have on vaping and smoking behaviours and attitudes?
- Among smokers and vapers, what is the effect of tank size on smoking and vaping behaviours?
- Among adults and youth how are public attitudes to vaping changing over time?
- Among people with mental health, how effective are EC compared to cigarettes in smoking cessation?
- Among discharged prisoners, what is impact of EC use in remaining abstinent from smoking post discharge?
- What is the demographic patterning of EC use (compared to smoking) and what are the implications for groups with high smoking prevalence?
- What are the effects of EC use in pregnancy, the unborn child and the neonate? Exposure levels, incidences of smoking-related effects such as low for gestational age birth weights, premature birth, sudden infant death syndrome, miscarriage and still birth.

Future considerations for research

Evaluating regulations

- In the general population what effect has TRPR had on poisonings and other accidents?
- Among non-smoking bystanders, what are the effects of tank size on consumption?
- Among consumers and bystanders, what is the effect of tank size on toxicant exposure?
- Among smokers and vapers, what is the effect of tank size on smoking and vaping behaviours?
- Among a) smokers b) vapers c) non smoker/non vapers, what are the effects of public vaping bans on toxicant exposure, smoking and vaping behaviours and (among non smoker/non vapers) attitudes?
- Among adults and youth, what is the role of price (and price relative to tobacco products) on vaping and smoking behaviours?

Wider population issues

- In groups with high smoking prevalence, what are the obstacles and enablers to switching from smoking to vaping?
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- How does EC interact with other TC policies such as tobacco tax, standard packaging etc?
- Among smoking and non smoking youth, what are the factors that predict vaping?
- What is the relationship between vaping and the de/renormalisation of smoking?

**Toxicology developments**
- Are there increases in exposure to hazardous chemicals as a consequence of EC sub-cultures e.g., sub-ohming, dripping and what are the health consequences?
- How safe are flavour components? Can sensitization occur through use in e-cig fluids?
- Also, for all of the comments above; How safe are heat not burn products?
- What are the levels of nanoparticles in EC aerosol and do these represent a health concern?
- What are the effects of EC use on populations with respiratory illnesses (asthma, COPD etc.)? Exacerbations of symptoms, improvements in symptoms compared with smoking? Interactions with inhaler medications?
Annex B

Department of Health e-cig studies funded by the Policy Research Programme (completed studies)

The Development of Tools to Measure Norms Towards Smoking, Nicotine Use, and the Tobacco Industry
[http://phrc.lshtm.ac.uk/project_2011-2016_013.html](http://phrc.lshtm.ac.uk/project_2011-2016_013.html)


UK Government e-cig funded programmes (in progress)

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<td>HTA - 12/167/135</td>
<td>A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service</td>
<td>Professor Peter Hajek/Queen Mary</td>
<td>Oct 2014</td>
<td><a href="https://www.journalslibrary.nihr.ac.uk/programmes/hta/12167135/#/">https://www.journalslibrary.nihr.ac.uk/programmes/hta/12167135/#/</a></td>
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<td>HTA - 13/155/05</td>
<td>Helping people cope with temptations to smoke to reduce relapse: A factorial randomised controlled trial</td>
<td>Professor Peter Hajek/Queen Mary</td>
<td>Apr 2016</td>
<td><a href="https://www.journalslibrary.nihr.ac.uk/programmes/hta/1315505/#/">https://www.journalslibrary.nihr.ac.uk/programmes/hta/1315505/#/</a></td>
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<td>PHR - 15/55/44</td>
<td>Evaluating graduated progress towards and impacts of the implementation of indoor smoke free prison facilities in Scotland</td>
<td>Professor Kate Hunt/ Glasgow</td>
<td>Sep 2016</td>
<td>[<a href="https://www.journalslibrary.nihr.ac.uk/programmes/phr/155544/#/">https://www.journalslibrary.nihr.ac.uk/programmes/phr/155544/#/</a>]</td>
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<td>PHR - 16/57/01</td>
<td>Impacts of e-cigarette regulation via the EU Tobacco Products Directive on young people’s use of e-cigarettes: a natural experiment</td>
<td>Dr Graham Moore/ Cardiff</td>
<td>Feb 2017</td>
<td>[<a href="https://www.journalslibrary.nihr.ac.uk/programmes/phr/165701/#/">https://www.journalslibrary.nihr.ac.uk/programmes/phr/165701/#/</a>]</td>
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