Introduction

The Royal College of Physicians welcomes this opportunity to submit evidence to the House of Commons Science and Technology Select Committee inquiry on e-cigarettes.

- 1. Smoking is the single largest avoidable cause of premature death¹ and one of the largest causes of health inequalities² in England. Every year, over 100,000 people in the UK are killed by smoking³, and although the proportion of people who smoke in the UK has fallen substantially over recent decades, 7.6 million UK adults remain regular smokers⁴. Half of these people will be killed by smoking unless they quit⁵. In addition to this burden of mortality, smoking currently causes approximately 474,000 hospital admissions each year⁶.
- 2. As demands on NHS and social services continue to increase, it has never been more important to support people to live healthier lives, reduce the prevalence of preventable illnesses and ease the pressure on the health service. This was made clear in the NHS's Five Year Forward View, which advocated a 'radical upgrade in prevention and public health'. With tobacco use still the foremost cause of preventable premature death in the UK, helping smokers to quit smoking is an obvious priority. The RCP has argued for over a decade that as a complement to conventional approaches to smoking prevention and services to help smokers to quit, it is also important to reduce the harm to smokers by enabling them to access products that offer them the nicotine they are addicted to, without the tobacco smoke that kills^{7,8,9}. Thus, in addition to encouraging as many smokers as possible to quit all tobacco and nicotine use, we should also be encouraging all those who are unable or unwilling to quit using nicotine, to switch to a smoke-free source of nicotine such as ecigarettes.
- 3. Many smokers have succeeded in quitting smoking simply by substituting tobacco cigarettes for ecigarettes. Whilst the long-term hazards of e-cigarette use will not conclusively be established for several decades, it is evident that e-cigarette vapour is a far less toxic carrier for nicotine than tobacco smoke and therefore far less likely to cause premature death or disability that tobacco smoking¹⁰. However, e-cigarettes have also proved to be highly controversial, attracting much

https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbrit ain/2016 [accessed 28 November 2017]

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¹ Office for National Statistics. Adult smoking habits in Great Britain: 2016. 2017.

² Jha P, Peto R, Zatonski W, Boreham J, Jarvis MJ, Lopez AD. 'Social inequalities in male mortality, and in male mortality from smoking: indirect estimation from national death rates in England and Wales, Poland, and North America.' Lancet. 2006 Jul–Aug;368:367–70.

³ Office for National Statistics. *Adult smoking habits in Great Britain: 2016.* 2017.

⁴. Office for National Statistics. *Adult smoking habits in Great Britain: 2016.* 2017.

⁵ Doll, R., Peto, R., Boreham, J., and Sutherland, I. *Mortality in relation to smoking: 50 years' observations on male British doctors.* BMJ, 2004; **328**: 1519-1533.

⁶ NHS Digital. 'Statistics on smoking: England 2017'. 15 June 2017. 79,000 deaths attributed to smoking per year divided by 365 days per year.

⁷ Nicotine without smoke - tobacco harm reduction. Royal College of Physicians, 2016.

⁸ Harm reduction in nicotine addiction. Royal College of Physicians, 2007. https://cdn.shopify.com/s/files/1/0924/4392/files/harm-reduction-nicotine-addiction.pdf?15599436013786148553

⁹Protecting smokers, saving lives. The case for a tobacco and nicotine regulatory authority. Royal College of Physicians, 2002. https://www.hri.global/files/2011/07/13/RCP - Protecting Smokers.pdf

¹⁰ Nicotine without smoke - tobacco harm reduction. Royal College of Physicians, 2016

criticism as well as support within medicine and public health, and indeed in wider society. The RCP therefore welcomes the independent inquiry announced by the Science and Technology Select Committee.

Summary of evidence

- 4. In 2016 the RCP published a report, 'Nicotine without smoke: tobacco harm reduction'¹¹, summarising the science, public policy implications, regulation and ethics of e-cigarettes and other non-tobacco sources of nicotine. The report addressed the common concerns expressed about e-cigarettes: that they might encourage the uptake of smoking among a new generation of smokers by acting as a gateway to tobacco; that e-cigarette use may 'renormalise' smoking; that their availability for dual use may result in sustained smoking among smokers who might otherwise have quit; that the potential health harms of sustained use are as yet unknown; and that this product group will be used by the tobacco industry to undermine tobacco control. The final conclusions of the report are as follow¹²:
- **E-cigarettes are not a gateway to smoking** in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco. Concerns about e-cigarettes helping to recruit a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded, although vigilant surveillance is required to ensure that the emergence of any such effect is detected and reversed promptly¹³.
- E-cigarettes do not result in the normalisation of smoking there is no evidence that either
 nicotine replacement therapy (NRT) or e-cigarette use has resulted in re-normalisation of smoking¹⁴
- **E-cigarettes and quitting smoking** e-cigarette use is likely to lead to quit attempts that would not otherwise have happened¹⁵.
- **E-cigarettes and long-term harm** the possibility of some harm from long-term e-cigarette use cannot be dismissed due to inhalation of ingredients other than nicotine, but is likely to be very small, and substantially smaller than that arising from tobacco smoking. Although it is not possible to estimate the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure¹⁶.
- E-cigarettes offer a useful tool to reduce the harm associated with tobacco. This must be supported by proportionate regulation which ensures product safety, enables and encourages smokers to use the product instead of tobacco, and detects and prevent effects that counter the overall goals of tobacco control policy.
- In the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK.

¹¹ Nicotine without smoke - tobacco harm reduction. Royal College of Physicians, 2016.

¹² Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016 p189-190

¹³ Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016 p119

¹⁴ Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016 p130

¹⁵ Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP, 2016 p129

¹⁶ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP p84

5. Since publishing the report in March 2016 the evidence base on e-cigarettes has expanded substantially but does not challenge or change the above conclusions. The RCP therefore continues to endorse the promotion of e-cigarette use as a substitute for smoking, to complement conventional tobacco control approaches already in place in the UK and to support the government objective of achieving a smoke-free generation¹⁷. The RCP welcomes the focus of the plan on reducing the burden of death and disease in disadvantaged groups and those with mental health conditions, and believes that promoting the use of e-cigarettes could make a substantial contribution to achieving these aims. The RCP would welcome the opportunity to provide oral evidence to the Committee on all of the above points.

The impact of e-cigarettes on human health

- 6. The market in non-tobacco nicotine products in the UK has been dominated for several decades by NRT such as trans-dermal patches, gum, lozenges, tablets, nasal and mouth sprays and inhalators. NRT is licensed as a medicine to help smokers quit smoking, and there is strong clinical evidence of their effectiveness. NRT is also licensed for use to help smokers cut down on smoking, and for temporary abstinence. NRT products have an excellent safety profile and present negligible risks to users. However, NRT products do not reproduce the rapid, high-dose delivery of non-tobacco nicotine products¹⁸ and reproduce few if any of the behavioural components of tobacco smoking. The dominance of NRT has been challenged in recent years by e-cigarettes, which are now more widely used than NRT.
- 7. E-cigarettes provide nicotine for inhalation in a vapour generated by heating a solution containing water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring. They deliver a much smaller range of toxins at much lower concentrations than cigarettes. The harm from e-cigarette use is therefore likely to be far less than that from smoking. However, some harm from long-term e-cigarette use cannot be dismissed. Repeated and sustained inhalation of the generally low concentrations of particulates, oxidants, carcinogens and other constituents could pose some risks to health, particularly in relation to Chronic Obstructive Pulmonary Disease (COPD) and lung cancer. However, the risk attributable to e-cigarette use is likely to be very small in absolute terms, and hence substantially smaller than that arising from tobacco smoking.
- 8. Similar to oral NRT products, reported short-term adverse effects relate predominantly to mouth and throat irritation, and tend to be self-limiting¹⁹ ²⁰ ²¹. As with all new products however, long-term or rare adverse effects will remain uncertain until e-cigarettes have been in widespread use for several decades. Areas of potential concern over the long-term effects of e-cigarette use

¹⁸ Brokowski L, Chen J, Tanner S. High-dose transdermal nicotine replacement for tobacco cessation. Am J Health Syst Pharm 2014;71:634–8. ¹⁹ Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* 2014;109:1801–10.

²⁰ Dawkins L, Corcoran O. Acute electronic cigarette use: nicotine delivery and subjective effects in regular users. Psychopharmacology 2014;231:401–7.

²¹ McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. Cochrane Database Syst Rev 2014;12:CD010216.

include the effects of vapour constituents depositing in the mouth, upper airway and lungs, and systemic effects of vapour components absorbed as a result of swallowing or inhalation. The vapour constituents to be considered include nicotine, propylene glycol, glycerine and flavours; those arising from impurities and contaminants in the e-liquid, which vary between batches and suppliers²²; and toxins, particles and other components created by the vaporisation process.

9. An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking²³, and a report by Public Health England (PHE) supported this conclusion²⁴. It should therefore be possible to reduce harm with appropriate product standards which will minimise toxin and contaminant exposure in e-cigarette vapour.

The effectiveness of e-cigarettes as a stop smoking tool

- 10. Around one in three smokers in the UK tries to quit each year, but only around one in every six of those who try to quit is successful²⁵. Most of those who try to quit do so without help, or until recently by using NRT bought over the counter. Over the past three years, however, e-cigarettes have become the most widely used aid to quitting.
- 11. Observational data suggest that those who use prescribed medication and behavioural support from a qualified stop smoking adviser (typically through NHS Stop Smoking Services (SSSs)) are two to three times more likely to succeed than those using no help²⁶. However, the number of people using NHS SSS has fallen by more than 60% from 816,444 in 2011/12 to 307,507 in 2016/17²⁷. The Smoking Toolkit Study, which provides information about smoking prevalence and behaviour in England, found that e-cigarettes have overtaken over-the-counter NRT as the first choice of stop smoking aid²⁸ and are 60% more effective in helping smokers quit than NRT bought over-the-counter or quitting unaided²⁹. The popularity of e-cigarettes has thus resulted in a substantial increase in the proportion of smokers using effective help to quit.
- 12. E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do use e-cigarettes have smoked in the past, or are current smokers. Long-term use of e-cigarettes among children who are not also experimenting with tobacco is rare.

²² National Institute for Health and Care Excellence. Tobacco harm reduction (PH45). London: NICE, 2013. www.nice.org.uk/PH45 [Accessed 9 November 2017].

²³ Nutt DJ, Phillips LD, Balfour D et al. Estimating the harms of nicotine

²⁴ McNeill A, Brose LS, Calder R et al. E-cigarettes: an evidence update. A report commissioned by Public Health England. London: Public Health England, 2015. https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update [Accessed 9 November 2017].

²⁵ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016.

 $^{^{26}}$ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016. p185

²⁷ NHS Digital. Statistics on NHS Stop Smoking Services: England, April 2016 to March 2017. Available: https://digital.nhs.uk/catalogue/PUB30058 [accessed 14 November 2017].

¹⁸ West, R. Electronic cigarettes in England: latest trends. Smoking Toolkit Study. 8 April 2014. http://www.smokinginengland.info/latest-statistics/ [accessed 14 November 2017]

²⁹ Brown J, Beard E, Kotz D, Michie S & West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Published online 20 May 2014. http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract

13. All the UK evidence, and almost all the international evidence on the use of e-cigarettes by children and young people to date indicates that concerns about e-cigarettes helping to encourage a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded³⁰. However, vigilant surveillance is required to ensure that the emergence of any such effect is detected and reversed promptly.

Regulation of e-cigarettes

- 14. The EU Tobacco Products Directive (TPD) came into effect in May 2017. The TPD is intended to introduce harmonised standards across the EU, improve the quality of products and reduce the risk of accidents, particularly in relation to children accidently drinking liquids or products leaking. To achieve this it includes a number of standards which products must meet. This includes rules on the nicotine concentration and tank size of electronic cigarettes. The maximum strength of nicotine allowed in e-liquid is 20 mg/ml, the maximum tank size will be 20ml and the maximum e-liquid bottle size is 10 ml. Although most high strength e-cigarettes will no longer be available, this will make little difference to consumers' vaping experience. A survey by Action on Smoking and Health (ASH) found that only 6% of vapers use nicotine above the TPD maximum of 20 mg/ml and only 1% of vapers use more than 10 ml of liquid a day.
- 15. It is a requirement of the TPD and the UK's Tobacco and Related Products Regulations³¹ that the impact of the regulations be reviewed and reported by May 2021 so that amendments can be developed and considered. In particular the TRPR commits to assessing whether the objectives of the regulations remain appropriate. PHE has also committed to carrying out an annual review of ecigarettes, the next of which is due to be published shortly.
- 16. Views vary widely both in the UK and internationally about the extent to which e-cigarettes should be regulated. A growing number of countries are introducing complete bans on e-cigarette sales, something the UK and the EU have not supported. E-cigarettes provide a useful aid to help people quit smoking, but they also contain nicotine which when rapidly delivered is highly addictive, and poor quality products can carry risks in terms of their safety and effectiveness. The provisions in the TPD are designed to address these concerns. Regulation is also an important part of reassuring current non-users about the relative safety of e-cigarettes. While there are already 2.9million regular e-cigarette users in Great Britain there are 7.6 million smokers³². Regulation should reassure those smokers who have not yet chosen to make the switch because of concerns over product quality, and help encourage them to do so.
- 17. The government must ensure that Brexit is not used an opportunity to weaken tobacco control legislation. The UK has adopted more stringent restrictions on tobacco than those required under EU law. This includes plain, standardised packaging for the sale of all tobacco products, the banning

 $^{^{30}}$ Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction. London: RCP, 2016. Chapter 7

³¹ The Tobacco and Related Products Regulations 2016. http://www.legislation.gov.uk/uksi/2016/507/contents/made [accessed 14 November 2017]

³² ONS: Adult smoking habits in the UK: 2016.

of smoking in public places and while children are present in cars. The RCP welcomes the government's intention to assess the TPD, including the ways in which it applies to e-cigarettes, and consider where Brexit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK³³.

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About the RCP

The RCP plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing almost 34,000 fellows and members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare. Our primary interest is in building a health system that delivers high quality care for patients.

³³ Department of Health. *Towards a Smokefree Generation A Tobacco Control Plan for England*. 2017