Introduction

1. NICE welcomes the opportunity to submit evidence to this inquiry on the impact of electronic cigarettes on human health (including their effectiveness as a stop-smoking tool), the suitability of regulations guiding their use, and the financial implications of a growing market on both business and the NHS.

2. This submission will focus on how we develop guidance and review evidence to produce our recommendations. In the context of e-cigarettes it will highlight relevant work we are carrying out to update smoking cessation guidance factoring in e-cigarettes, including the evidence our independent guideline committee has looked at so far.

3. We will set out our position on e-cigarettes in the guidance we will publish in 2018.

Background

4. Smoking is the main cause of preventable illness and premature death in England, with an estimated 475,000 NHS hospital admission in England linked to smoking-related conditions in 2014/15, primarily related to cardiovascular and respiratory diseases. An estimated 17% (78,000) of all deaths in 2014 were attributed to smoking. Treating smoking related illness is thought to cost the NHS £2.5 billion per year with the estimated cost to society being £12.7 billion.

5. Many people try to quit smoking using a variety of methods with a combination of evidence-based pharmacotherapy and behaviour support being the most effective way to help people stop smoking.

E-cigarettes and licensing

6. An electronic cigarette or e-cigarette is a handheld electronic device that vaporises a liquid. The user inhales the vapour. The liquid is usually made of nicotine, propylene glycol, glycerine, and flavourings. Some e-liquids do not contain nicotine. Although e-cigarettes are not licensed medicines, they are regulated by the MHRA under the Tobacco and Related Products Regulations 2016.

7. In the UK only licensed e-cigarettes are approved for health use with a therapeutic indication for smoking cessation (or harm reduction). To date, one product has been approved as a licensed medicine in the UK, but has not yet been brought to market.

How NICE develops guidance
8. NICE guidance makes evidence-based recommendations based on the best available evidence of what works, and what is cost effective. We use a wide range of different types of evidence and other information – from scientific research using a variety of methods, to testimony from practitioners and people using services. Guidance is developed by independent committees of experts that include lay members. The guidance development process includes regular consultation that allows organisations and individuals to comment on our draft recommendations before final publication. NICE guideline recommendations normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. Once published, all NICE guidance is regularly checked and updated in light of new evidence if necessary. NICE is committed to advancing equality of opportunity and ensuring that social value judgements we make reflect the values of the society our guidance is aimed at.

NICE guidance on e-cigarettes

9. Electronic cigarettes have been increasingly used as an aid to stop smoking and in 2017, NICE reviewed the current evidence for the effectiveness of licensed e-cigarettes as a smoking cessation aid as part of its update to current guidance. The guidance covers stop-smoking interventions and services delivered in primary care and community settings for everyone over the age of 12. The recommendations focus on vulnerable groups who find it hard to quit or who smoke a lot. The proposed recommendations have undergone public consultation and the final guidance is due to be published in March 2018.

10. The guideline committee have reviewed evidence on the effectiveness of licensed e-cigarettes in the context of pharmacotherapies for quitting smoking and advice for consumer e-cigarettes. Questions asked about e-cigarettes for this evidence review were:

- Are nicotine replacement therapy (such as patch, gum, spray or licensed e-cigarettes) or bupropion, on their own or combined with behavioural support, effective and cost-effective?

- What advice and referral options are appropriate for people using consumer e-cigarettes (or similar consumer electronic nicotine delivery systems)?

NICE draft recommendations on e-cigarettes

11. The following draft recommendations have been made by NICE on e-cigarettes in its update to the guidance.
Advice

1) Offer advice on using nicotine replacement products on general sale including e-cigarettes (recommendation 1.3.8)

2) Ask people about their use of nicotine-containing e-cigarettes and explain that:

   a. Although these products are not licensed medicines, they are regulated by the Tobacco and Related Products Regulations 2016

   b. Some smokers have found them helpful to quit smoking cigarettes and

   c. There is currently little evidence on the long-term benefits or harms of these products (recommendation 1.3.9)

Be aware that Public Health England and the Royal College of Physicians have stated that e-cigarettes are significantly less harmful to health than tobacco.

12. These recommendations were made based on evidence from a systematic literature review and expert testimony. The systematic literature review included one Cochrane review (Hartmann-Boyce et al 2016). There was weak positive evidence from this review that licensed e-cigarettes helped smokers to stop smoking. The evidence that e-cigarettes are effective in smoking cessation in England is limited, drawing mainly upon observational data. Observational data from the UK suggest that there has been an increase in the popularity of e-cigarettes accompanied by a reduction in smoking cigarettes.

13. E-cigarettes appear to be less harmful than smoking. However, there was no published evidence on the long-term benefits or toxicity of e-cigarettes, and no evidence on the long-term toxicity on those exposed to second-hand vapour.

14. There was no published evidence on advice and referral options for people using consumer e-cigarettes for smoking cessation.

15. However, the committee noted that evidence on licensed products was for out-of-date technologies and were carried out in non-UK based settings. They also noted that there are currently no licensed e-cigarettes currently available in the UK. E-cigarette research is a rapidly moving field and the committee noted that there are ongoing studies of new e-cigarette technologies in the context of UK stop smoking services and so did not draft a recommendation on licensed e-cigarettes. The committee also heard that there is a split among cessation professionals internationally over the benefits of offering advice on nicotine-
containing e-cigarettes. Some experts have also expressed concern about the ‘gateway’ effect of e-cigarettes, but data are lacking.

16. No review of cost-effectiveness was undertaken. A bespoke model that was able to use data from a meta-analysis of two studies of licensed e-cigarettes indicated that e-cigarettes were cost-effective and potentially cost saving to both the NHS and local authorities.

Research recommendations

17. The guideline committee also made a research recommendation on consumer e-cigarettes. The research recommendations process translates uncertainties in the evidence into research recommendations.

1) How effective and cost effective are consumer (non-prescription) e-cigarettes in helping people to stop smoking and to prevent relapse.

18. This recommendation was made on the basis that the committee felt that there was paucity of evidence to understand whether consumer e-cigarettes are an effective aid to quitting smoking in both the short and long term, and for whom (especially in disadvantaged groups), as part of self-help or through local stop smoking services. Additionally to determine whether they help people switch completely or partly (dual use) from tobacco cigarettes, prevent relapse, and if there are as yet unknown adverse effects.

Conclusion

19. The NICE guidance on e-cigarettes suggests that some smokers have found e-cigarettes helpful to quit smoking cigarettes. E-cigarettes appear to be less harmful than smoking. However, there are limited data on the long-term effectiveness and cost-effectiveness of e-cigarettes as an aid to smoking cessation and no data on long-term benefits or harms. A further research recommendation has been made. Evidence on e-cigarettes as a harm reduction aid have not been explored.

20. Further details are provided in the NICE guidance and evidence reviews attached as appendices to this submission.

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