

## POSITION STATEMENT: E-Cigarettes

The Lancashire Medicines Management Group does not recommend the prescribing of E-Cigarettes.

### 1. BASIS FOR THE RECOMMENDATION

E-cigarettes have developed relatively recently as a popular substitute to smoking tobacco. Historically they have been unregulated however; under the revised EU Tobacco Products Directive which came into force in May 2016 e-cigarettes will be regulated as consumer products unless the manufacturer chooses to seek a medicinal licence.

The first licensed e-cigarette, e-Voke®, was granted a marketing authorisation in November 2015 with the indication *'to relieve and/or prevent withdrawal symptoms and reduce the cravings associated with tobacco dependence.'* The launch of e-Voke® is expected to be sometime in 2016 and it is likely that further e-cigarette products will follow. It is anticipated that when it is launched that there will be a significant demand for General Practitioners to issue prescriptions.

It is noted that NICE Public Health Guideline 45, Smoking: harm reduction (June 2013) recommends that licensed nicotine-containing products, should be offered to people who smoke and wish to reduce their cigarette consumption as well as those planning to stop completely.<sup>1</sup> It is recognised that some people may wish to use e-cigarettes in the longer term in a similar way to help reduce smoking. However, at the time of publication, NRT products were licensed as medicinal products, therefore e-cigarettes were not considered as part of this recommendation.

To date the evidence around the potential benefits and risks of e-cigarettes, particularly around long-term use, is still accumulating. There is also a lack of data to demonstrate the benefits of using the e-Voke® device, with no published trials using e-Voke®. The clinical study submitted to support the licensing application was a pharmacokinetic study and did not include any evidence of effectiveness. Further data is required to evaluate the use of e-Voke® and to compare its use to other nicotine replacement therapies (NRT) that are currently used within the NHS. Robust safety data is also needed.

Therefore due to a lack of data to demonstrate the benefits of using the e-Voke® devices, e-Cigarettes are not recommended for prescribing by the Lancashire Medicines Management Group.

**Smoking Cessation Services, including those provided by community pharmacy, are commissioned by other agencies. The decision to use e-cigarettes as part of these services is theirs alone.** GPs should not be asked to prescribe e-cigarette for patients as part of their service. Prescribing in these circumstances could result in displacement of other treatments for which the CCG is the responsible commissioner. Patients presenting at GP surgeries requesting e-cigarettes can be referred to local stop smoking services for advice and support.

### Supporting Information

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## E-cigarettes

**Evidence:** The evidence base on e-cigarettes is still developing and longer term data is needed to fully understand the safety of these products. **The Cochrane Review - Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe for this purpose**<sup>1</sup> concluded that quality of the evidence for the use of e-cigarettes to help people stop smoking is overall low by GRADE standards because it is based on only a small number of studies with low event rates and wide confidence intervals around the estimated mean. The lack of difference between the effects of e-cigarettes compared with nicotine patches found in one trial is uncertain for similar reasons. Lack of biochemical assessment of the actual reduction in smoke intake further limits this evidence. It was considered that more studies of e-cigarettes are needed.

### e-Voke®

**Evidence:** The manufacturer of e-Voke submitted a “hybrid medicine” application for the licensing process. This is similar to a generic application, i.e. based on a reference medicine, but presented as a different formulation/device. This method of application only requires the manufacturer to provide information on the quality of the medicine and supply data to demonstrate bioequivalence with the reference medicine i.e. Nicorette® inhaler. No published trials using e-Voke® were provided, however a clinical study was submitted to support the marketing authorisation application<sup>2</sup>. This was a pharmacokinetic study with a crossover design, comparing bioavailability of nicotine, in 24 adult males, when delivered by e-Voke® 10mg or 15mg cartridges, Nicorette® 15mg Inhalator or smoking a Benson and Hedges Gold cigarette. The levels for e-Voke® were found to fall between those of the Nicorette inhaler and a cigarette. No further efficacy data was required or submitted for the licensing application This study did not include any evidence for effectiveness in smoking cessation

**Safety:** The pharmacokinetic study concluded that the peak plasma levels of nicotine in the e-Voke® inhaler products are lower than those with normal cigarette use. This indicates that these products can be considered at least as safe in terms of nicotine consumption as cigarette smoking. There did not appear to be additional adverse event reporting following four administrations of e-Voke® over a period of 3 hours.

No other safety events or outcomes were reported.

No length of treatment course maximum or otherwise is recommended in the SPC. There is no data for safety in long-term use including inhalation of additives or on passive inhalation of vapour. For side effects and contra indications see the Summary of Product Characteristics SPC

**Cost:** A price for e-Voke® is not yet available. Estimates propose a cost of £20 per kit and £10 for refills – this equates to approximately £600 per patient per year 3.

As this could involve a large cohort of patients, if patients are prescribed e-Voke® on a long term basis this could have a significant impact on the health economy and may displace other treatment.

**Patient Factors:** e-Voke® along with other e-cigarettes will be available to purchase by patients should they favour the use of an e-cigarette, however those patients that want to quit and require nicotine replacement therapy will be offered more established NRT alongside support by the local stop smoking service which have been proven to be the most effective way to quit smoking altogether.

## REFERENCES

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1. Cochrane Library – Can electronic cigarettes (ECs) help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? December 2014. Accessed 09 June 2016 at [http://www.cochrane.org/CD010216/TOBACCO\\_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose](http://www.cochrane.org/CD010216/TOBACCO_can-electronic-cigarettes-help-people-stop-smoking-or-reduce-the-amount-they-smoke-and-are-they-safe-to-use-for-this-purpose)
2. MHRA UKPAR trial summary e-Voke 10mg electronic inhaler and e-voke 15mg electronic inhaler Nicovations Ltd Accessed 09 June 2016 at <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con616843.pdf>
3. Northern (NHS) Treatment Advisory Group- Treatment Appraisal: Decision Summary e-Voke® (Nicovations Ltd) electronic cigarette. Accessed 23 June 2016 at <http://ntag.nhs.uk/docs/rec/NTAG-Recommendation-e-Voke-e-cigarette.pdf>