Department of Health position on electronic cigarettes

Summary

1. The UK Government's position on nicotine containing products, including electronic cigarettes, is to enable the availability of products that meet appropriate standards of safety, quality and efficacy to help reduce the harms from smoking. Proportionate regulation is necessary to meet public health objectives. This can be achieved by medicines regulation. An additional route to a regulated market will be provided by the Tobacco Products Directive, once transposed in 2016/17.

Background

2. The Government's position on the regulation of nicotine containing products, including electronic cigarettes, has been the subject of cross Government consideration and a full public consultation. To inform how this work was taken forward, an expert working group was set up under the Commission on Human Medicines (CHM). The group devised a programme of work to scope:

- the nature, quality and safety of unlicensed NCPs,
- the actual use of unlicensed NCPs in the marketplace,
- the effectiveness of unlicensed NCPs in smoking cessation, and
- modelling of the potential impact of regulation on public health outcomes.

Stakeholder engagement

3. During the course of 18 months, the MHRA met with a wide range of stakeholders including across central and local government, industry, researchers, Action on Smoking and Health, the British Medical Association and medical royal colleges.

Evidence considered

4. The CHM advised on the MHRA's assessment of all the available data, from published and unpublished studies and from research on products on the UK market commissioned by the MHRA. Information from surveys and qualitative data was brought together to provide an analysis of how electronic cigarettes are used in practice and the potential for public health benefit.

5. The Government has accepted the advice of the CHM and its expert group, which concluded that NCPs currently on the market do not meet appropriate standards of safety, quality and efficacy. Testing data confirm that nicotine levels can vary considerably from the labelled content and the amount of nicotine per product can differ from batch to batch. In terms of how well NCPs work, there can be widely differing amounts of nicotine from the same format with one form delivering what could be an effective therapeutic dose, another a "placebo" dose. With regards to safety, toxic elements may be included at unexpectedly high doses which could produce adverse effects, particularly in vulnerable patient groups.

6. The consistent evidence from a variety of sources is that most electronic cigarettes use is to support stop smoking attempts or for partial replacement to reduce harm associated with smoking. The current evidence is that electronic cigarettes have shown some promise in helping smokers quit tobacco but the quality of existing NCPs is such that they cannot be recommended for use.

7. The public health priority of reducing the harms of smoking is not supported by the current regulatory framework, under the general product safety regulations. To manage the risk of poor and ineffective products and to maximise the potential for public health gain, NCPs should be regulated as medicines to ensure that:

- Standards of quality, safety and efficacy are met
- Monitoring safety in use, including over the long term, is provided for
- Advertising of NCPs is controlled through medicines provisions
- And any emerging risks can be effectively managed.

Tobacco Products Directive

8. The Government supported the final text of the revised Directive which provides for additional safeguards to existing consumer product provisions, in relation to safety, quality, ingredients and presentation of electronic cigarettes, where these are not licensed as medicines. These are summarised in the table below.

9. It was not possible to achieve age of sale controls through the revised Directive so the Government has already moved quickly to take regulation-making powers to prohibit the sale of e-cigarettes to under-18s, through the Children & Families Act. The Government will consider what scope there is for further controls on e-cigarettes including, for example, advertising and promotion in the domestic market.

Conclusion

10. The MHRA is currently considering applications for licensed electronic cigarettes and there is considerable interest from industry in seeking to license products. The Department of Health will work with stakeholders on the transposition of the TPD. Following transposition of the revised directive in 2016, only electronic cigarettes which are licensed as medicines or meet the requirements of the TPD, will be allowed on the UK market.

Table 1

Characteristics of regulation under MHRA and TPD	
Tobacco Products Directive regulation of electronic cigarettes	**MHRA licenced Nicotine Containing Products (NCPs) including e-cigs**
Products not available on prescription	Products available on prescription
20% VAT	5% VAT
Cross border advertising banned by 2016, up to MS to decide on domestic advertising (billboards, PoS, buses etc.)	Advertising allowed – under OTC rules so no celebrity endorsement, free samples and must be targeted at adult smokers etc.
Products widely available	Products available on general sale (GSL)
Can't make health claims	Can make health claims
Upper limits for nicotine content will be set and likely to be in force by 2017.	MHRA regulation is flexible there are no upper limits.
30% health warning on packs about nicotine on front and back of packs	No health warnings on packs
Member States retain powers e.g. on flavours, domestic advertising.	Flavours require a marketing authorisation
Children and Families Bill allows for age of sale of 18 for nicotine products.	Age of sale 12 but can be varied by product so could be higher for e-cigs.