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 Editorial: Electronic cigarettes as a method of tobacco control (BMJ 2011;343:d6269)

MEDICAL DEVICE OR CONSUMER PRODUCT?

As the UK considers regulating e-cigarettes, **Jonathan Gornall** asks whether this is good news for public health



Electronic cigarettes hit the headlines in July when a concerned member of the public travelling on a coach on the M6 toll motorway in the Midlands called police to say he had seen “smoke” issuing from a bag into which a fellow passenger had been pouring an unknown liquid.

Fearing this was a terror incident, armed police stopped the coach, evacuated the passengers, and closed the motorway before finally declaring the bag and its contents—an e-cigarette and associated paraphernalia—harmless.

It is taking the UK Medicines and Healthcare Products Regulatory Agency rather longer to come to the same conclusion—or, rather, to determine whether the devices should be treated as medicinal products, regulated accordingly, and subject to MHRA medicines marketing authorisation.

The e-cigarette is designed to look and behave like a cigarette but delivers only vaporised nicotine and none of the toxins associated with tobacco to its users, who call themselves vapers rather than smokers. When the user sucks on the device, an atomiser powered by a battery heats and vaporises a mixture of nicotine and propylene glycol, a compound with a wide range of commercial uses, including in theatrical “smoke” machines. A written Commons statement by health minister Simon Burns in July suggested they were used by as many as 650 000 in the UK.¹

Legal status

Currently any nicotine containing product that claims or implies it can help users to give up smoking is deemed by the MHRA to be a medicinal product. The makers of e-cigarettes do not claim that their products help smoking cessation, but the MHRA seems determined to close what it sees as a regulatory loophole and hopes to reach a decision by next spring.

Crucially, the MHRA is also seeking to model “the potential impact of bringing these products into medicines regulation on public health outcomes.” This has proved a keen concern, both

among users of e-cigarettes and professionals from public health organisations, worried that any restriction in the availability of e-cigarettes could see users return to real cigarettes, adding to the toll of 80 000 lives lost prematurely each year through the use of tobacco products.

Patterns of use

John Britton, director of Nottingham University's Centre for Tobacco Control Studies, says that most people who use e-cigarettes do so “either as a temporary substitute to smoking tobacco or as a long term substitute and eventually quit.”

Without doubt, he says, such devices “have a huge amount to offer public health, potentially.” But at the same time “you want consumers and health professionals to be secure in the knowledge that what they are buying contains what it

says it contains and meets acceptable standards of safety, quality and consistency.”

If e-cigarettes were regulated as medicinal products, each type would have

to undergo evaluation by the MHRA for quality, safety, and efficacy. The MHRA, which insists it “does not want to see useful products removed from the market,” nevertheless recognises that this “will have an economic impact on importers of these products” and even that some companies could go out of business. However, regulation “could make such products more widely available,” it suggests; general sale legal status would mean e-cigarettes could be sold in general sale outlets, such as supermarkets, where they would be “supported by clear information for users and appropriate advertising.”

Industry resistance

For its part, an industry that has grown swiftly over the past few years is reluctant to see its products regulated as medicinal and insists their safety is ensured by general product safety laws.

“If the MHRA attempts to regulate e-cigarettes under a medicinal regime we will seek legal redress,” says Katherine Devlin, president of the

Electronic Cigarette Industry Trade Association, which has 22 members, mainly from the UK.

Compliance with MHRA licensing, she says, “would cost so much per product and would necessitate a fundamental shift in how the products are put together and operate, which would restrict the current freedom of choice that consumers have.”

Regulation, however, seems likely. The MHRA says the e-cigarette is a medicinal product as defined by article 1 of European directive 2001/83/EC on the code relating to medicinal products for human use. Also, a spokesman said that available data suggested that the quality or efficacy of e-cigarettes could not be guaranteed.

“The release of nicotine from the same e-cigarette can vary over time, and the amount of nicotine per product might not be the same from batch to batch,” he said. In addition, “toxic elements may be included and unexpectedly high doses of nicotine could produce adverse effects, particularly in some vulnerable patient groups.”

The MHRA has quoted laboratory analysis by the US Food and Drug Administration (FDA), in which “samples were found to contain carcinogens and toxic chemicals, against which general product safety legislation could not protect.”³ On the other hand, it recognises that harm reduction should be included as an indication for nicotine replacement therapy “since it has become widely accepted that there are no circumstances in which it is safer to smoke than to use NRT.”⁴

In America, where tobacco products cause over 400 000 premature deaths a year, the FDA has been obliged to take a different approach—and one that might encourage the UK industry's resistance to the MHRA's plans in the UK. Last year, after an initial attempt by the FDA to regulate e-cigarettes as medical devices was challenged by a manufacturer and met defeat in court, it announced that, in accordance with the decision by the US Court of Appeals, it was now planning to regulate them as a tobacco product.⁵

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References are in the longer version on bmj.com.

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