



Chartered
Institute of
Environmental
Health

Regulation of Nicotine Containing Products

Response to Consultation by Medicines and Healthcare
products Regulatory Agency (MHRA)

28 May 2010

The Chartered Institute of Environmental Health

As a **professional body**, we set standards and accredit courses and qualifications for the education of our professional members and other environmental health practitioners.

As a **knowledge centre**, we provide information, evidence and policy advice to local and national government, environmental and public health practitioners, industry and other stakeholders. We publish books and magazines, run educational events and commission research.

As an **awarding body**, we provide qualifications, events, and trainer and candidate support materials on topics relevant to health, wellbeing and safety to develop workplace skills and best practice in volunteers, employees, business managers and business owners.

As a **campaigning organisation**, we work to push environmental health further up the public agenda and to promote improvements in environmental and public health policy.

We are a **registered charity** with over 10,500 members across England, Wales and Northern Ireland.

Any enquiries about this response should be directed in the first instance to:

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Introduction

The Chartered Institute of Environmental Health (CIEH) welcomes this opportunity to comment on the MHRA consultation on the proposed regulation of nicotine containing products.

We have constructed our response in three parts:-

Part 1 provides background information on our concerns and activities relating to nicotine replacement products.

Part 2 contains our specific comments on the proposals for regulation and our support for Option 1.

Part 3 contains our particular concerns regarding so called 'electronic cigarettes'.

Part 1

1. Background information on our concerns relating to nicotine replacement products

- 1.1 The CIEH is concerned to support any measures which can help to ensure that people are protected from the harmful effects of second-hand tobacco smoke and we therefore fully support the use of nicotine containing products where they have been demonstrated to be effective and safe.
- 1.2 The CIEH has fully supported the work of the National Institute for Health and Clinical Excellence (NICE) in this area. We were represented on the Programme Development Board of NICE which examined the use of smoking cessation methods and products, including nicotine replacement therapy. The findings and recommendations were published as NICE Public Health Guidance 10: *Smoking cessation services in primary care, pharmacies, local authorities and work places, particularly for manual working groups, pregnant women and hard to reach communities*, February 2008. Our representative was also identified as an expert co-optee to the NICE Public Health Interventions Advisory Committee (PHIAC) which was concerned with public health guidance on workplace health promotion with reference to smoking and what works in motivating and changing employees' behaviour. The findings and recommendations were published as NICE Public Health Intervention Guidance 5: *Workplace health promotion: how to help employees to stop smoking*, April 2007.
- 1.3 Our advice to all members of the environmental health profession is that they should maintain basic knowledge of, and be willing to promote the use of, smoking cessation services.
- 1.4 The CIEH is a founding member of the Smokefree Action Coalition and supports the following position statements promoted by Action on Smoking and Health (ASH):-
 - 1.4.1 Tobacco smoking remains the single biggest cause of illness and premature death in the UK. Whilst from a public health perspective the preferred outcome must continue to be complete smoking cessation, it is recognised that relapse is high and nicotine addiction is so strong, that a harm reduction approach which helps smokers switch from dangerous smoked tobacco products to safer alternative nicotine delivery devices needs to be supported and encouraged since most of the harm comes from inhaling tobacco smoke.
 - 1.4.2 In addition, the Government's strategy 'A Smokefree Future' recognises the importance of a harm reduction approach in supporting smokers to:-
 - cut down their levels of smoking before completely quitting
 - manage their nicotine addiction, using a safer alternative product, when they are unable to smoke
 - dramatically reduce their health harms, and the harms to those around them, by using a safer alternative to smoking
 - 1.4.3 A harm reduction policy has the added benefit of protecting non-smokers, particularly children, from illnesses caused by passive smoking. Children's exposure to second-hand smoke currently results in more than 300,000 GP consultations and about 9,500 hospital admissions every year in the UK.

Part 2

2. Specific comments on the proposals for regulation

Support for Option 1

- 2.1 Nicotine containing products (NCP) are already extensively available and widely promoted, including via the internet. As well as nicotine they may contain other toxic constituents.
- 2.2 Doing nothing and continuing to allow these unregulated products to remain on the market is not an acceptable situation and is a risk to public health. In reaching this position we have particularly taken notice of your statement:-
 - 2.2.1 *NCPs cannot guarantee quality; the release of nicotine from the same NCP over time can vary with reduction over time indicating instability throughout its shelf life and the amount of nicotine/product might not be the same from batch to batch. In terms of efficacy there can be widely differing amounts of nicotine from the same format (i.e. patch, orally, via an electronic cigarette) with one form delivering what could be an effective therapeutic dose, another a 'placebo' dose. With regards to safety, toxic elements may be included and unexpectedly high doses of nicotine could produce adverse effects, particularly in some vulnerable patient groups such as those with cardiovascular disease (paragraph 16).*
- 2.3 We believe that bringing all current unlicensed NCPs into regulation would address these issues and ensure that smokers had access to products of the requisite quality, efficacy and safety to eliminate or reduce the harm from smoking.
- 2.4 The CIEH therefore supports the proposal that the MHRA should consider all products containing nicotine to be medicinal products by function on the basis that it is necessary and justifiable for them to be assessed for safety, quality and efficacy.
- 2.5 It follows that, having accepted the justification for classifying all such products containing nicotine as medicinal under the Marketing Authorisation Regulations, it is then logical that they should be brought within the normal arrangements for control. We therefore support the intention that, in line with current practice, there would be an immediate requirement for cessation of the sale or supply, with written confirmation of the same within 21 days.
- 2.6 We understand that it would then be for each manufacturer to provide relevant evidence to support the submission of an application for a Marketing Authorisation to the MHRA for approval.
- 2.7 We further support the intention that, by requiring that all products containing nicotine are to be regulated by function, then both presentation and the indications for such products would automatically be regulated as well.

Part 3

3. Particular concerns regarding so called 'electronic cigarettes'

- 3.1 As the MHRA will be aware, electronic battery powered vaporising electronic cigarettes (electronic cigarettes) containing nicotine, have become widely available in recent years. There are also 'electronic cigar' versions. There are reports that they are being sold on aeroplanes during flight, given away as prizes in Bingo Halls and at least one publican stated in court that he was lending them out to patrons. They are also being used by patients in mental health units where it is known that nicotine levels in a person can have a serious effect on the efficacy of medication.
- 3.2 The use of these electronic cigarette products is not included within the definition of 'smoking' in the Health Act 2006. The definition of tobacco in the Children and Young Persons Act 1933, as amended, does not include electronic cigarettes, neither are these devices captured by any of the consumer protection legislation which controls the sale, promotion, advertising and labelling of tobacco products.
- 3.3 In order to be sold legally in the UK, electronic cigarettes are required to meet the requirements of the General Public Safety Regulations 2005 and associated safety regulations. However, research carried out by local authority trading standards officers has shown that many brands commonly available in the UK fail to meet these requirements. A number of safety concerns have come to light including electrical safety, and the need for adequate hazard labelling in respect of the nicotine content, and the provision of child resistant packaging for the nicotine cartridges. There are no recognised standards or safety specific regulations for this product and it is very likely that variations of the electronic cigarette will continue to appear in the market place requiring individual testing to assess compliance with product safety legislation.
- 3.4 There is no existing legislation to deal with electronic cigarettes as age-restricted products and therefore they can be legally sold to young persons of any age. This is in stark contrast to the legislation controlling for example, tobacco products, alcohol, solvents and fireworks all of which are age-restricted in order to protect the wellbeing of young people.
- 3.5 There are therefore major concerns about access to electronic cigarettes by young people, given the nature of the product in that it contains a highly addictive substance, nicotine, and the likely appeal of the product which is usually either brightly coloured or closely represents a real cigarette, with an end that lights up and it may eject a vapour which allows the user to simulate smoking.
- 3.6 The MHRA will be aware that no approval has been given for these products and yet there have been instances of their use being advocated for medicinal purposes and for treating smoking addiction.
- 3.7 It is therefore apparent that the suppliers of these products are by-passing all of the legislative controls that are in place to deal with conventional and substitute tobacco products. This is a cause of serious concern amongst local authority officers who are usually relied upon to safeguard the public in such circumstances. Their concerns have been supported by CIEH, the Trading Standards Institute and LACORS and these organisations have made collective representations to the Department of Health (see attached copy of letter dated 3 September 2009).