

Pharmaceutical Society of Northern Ireland
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7 February 2013

Dear registrant

The Standards Committee of the Pharmaceutical Society NI has issued the following statement on electronic-cigarettes (e-cigarettes). Please note that this position reflects current UK and EEA legislation as well as the professional guidance of the Pharmaceutical Society NI.

An e-cigarette is a battery-powered product that vaporizes a liquid solution into an aerosol mist, simulating the act of tobacco smoking. Many e-cigarettes contain a nicotine solution and these are available from manufacturers in varying strengths.

E-cigarettes are not currently recognised as medicines or medical devices and are therefore not regulated as such, and have no marketing authorisation from the Medicines and Health products Regulatory Agency (MHRA)¹. The MHRA is currently working with experts on the Commission on Human Medicines, to consider the evidence base for e-cigarettes and their usage and will make a decision on their regulation in spring 2013.

In the standard of the **Code of Ethics for Pharmacists in Northern Ireland (2009)**, registrants are reminded of their obligations of conduct, as well as, their responsibilities of professional and practice performance, in particular, **principle one** which states that as a registrant you must '**make the safety and welfare of patients your prime concern**'^[1]. Based on this principle and its corresponding obligations, it is for every pharmacy owner, responsible pharmacist or superintendent pharmacist and pharmacist, to use their professional judgement to decide if they are confident to recommend e-cigarettes for sale via their community pharmacy after taking into account the evidence-base and other relevant guidance associated with their use.

¹ Medicines and Health products Regulatory Agency (MHRA) is a government appointed agency responsible for ensuring that medicines and medical devices are safe for use by the public.

1. <http://www.psni.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf>

Further, the Pharmaceutical Society NI notes that on 19 December 2012, the European Commission adopted a proposal to revise the Tobacco Products Directive. The revised directive is expected to be adopted in 2014 and come into effect from 2015-2016.

The proposed legislation will consist of new and strengthened rules on how tobacco-containing products can be manufactured, presented and sold in the EEA and this legislation will also affect the regulation of e-cigarettes.

Some of the rules being proposed are that:

“Nicotine Containing Products (e.g. e- cigarettes), below a certain nicotine threshold are allowed on the market, but must feature health warnings; above this threshold such products are only allowed if authorized as pharmaceutical products, like nicotine replacement therapies.

Herbal products used for smoking will have to carry health warning labels to inform about their risks.”

Please follow the link for further information:

http://ec.europa.eu/health/tobacco/products/revision/index_en.htm

For further information please contact, Michelle McCorry at:

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Yours sincerely

Mark Nelson
Chair of Standards Committee

Brendan Kerr
Registrar