PSI
THE PHARMACEUTICAL SOCIETY OF IRELAND
Cumann Cógaiseoirí na hÉireann
THE PHARMACY REGULATOR

PSI position on electronic cigarettes

The PSI has recently received a number of inquiries regarding the appropriateness of electronic cigarettes (e-cigarettes) being offered for sale or supply in retail pharmacy businesses, as these products are not currently regulated under either the medicinal products or medical devices legislation.

In addition, the supply of these products in pharmacies requires consideration under the PSI Code of Conduct, as pharmacists should ensure that products supplied do not pose a hazard to a patient's health or well-being.

Electronic cigarettes

Electronic cigarette products are typically presented in two parts, one of which is a device and the other a fill or refill consisting of a solution of various compositions containing Nicotine. These products are not currently being regulated under the medicinal products legislation, medical devices legislation or tobacco legislation. It should be noted that they do come within the scope of the Waste Electrical and Electronic Equipment (WEEE) Directive.

Agreement has not yet been reached as to the legal classification of these products, i.e. whether they are medicinal products that would require appropriate marketing authorisation, or whether they are medical devices, in which case an appropriate notification to an EU competent body would be required, including appropriate labelling, before being placed on the market.

EU Position

The PSI understands that the EU Commission has recently commenced a public consultation with respect to the possible revision of the Tobacco Products Directive 2001/37/EC, and that one of the issues being considered is the extension of the scope of that Directive to cover electronic nicotine delivery systems where such products are presented as alternatives to cigarettes. It has also been noted that these kinds of products have the potential of undermining smoking cessation policies, since they keep the smoking addiction (EC Orientation Note on Electronic Cigarettes, May 2008*).

This EC Orientation Note also gave consideration to whether or not these products can be characterised as human medicines and thereby requiring regulation as authorised medicinal

products. It stated that where such products are presented for use in or to assist in smoking cessation, they are regarded as medicinal products. This means that such products would be required to be the subject of a marketing authorisation before being placed on the market in Ireland, and this would be a particular issue if they were to be supplied through retail pharmacy businesses.

Under the heading *Human medicine by presentation,* the EC Orientation Note states that a product is also presented as a medicinal product whenever any averagely well-informed consumer gains the impression that the product in question should, having regard to its presentation, have the properties for treating or preventing disease in human beings. In this context, presentation would include recommendations for use given via the labelling, leaflets or verbally.

PSI guidance to pharmacists and retail pharmacy businesses

In the absence of appropriate regulation (i.e. as medicinal products or as medical devices), the PSI considers that it would not be appropriate for any of these products to be offered for sale or supply in retail pharmacy businesses in Ireland. Members of the public have a right to expect that the quality, safety and efficacy of any such products supplied in pharmacies have been appropriately established and independently assured.

In addition, pharmacies and pharmacists play an increasingly important role in the provision of public health protection information and services to the public, including information, services and advice on smoking cessation.

Under the Code of Conduct, pharmacists are required to ensure that products supplied to patients do not pose a hazard to a patient's health or wellbeing, as may be the case if a person were to resort to a particular product in respect of which the safety and efficacy had not been established against other products and treatments that have met the required standards of safety and efficacy.

* EC Orientation Note on Electronic Cigarettes, May 2008, accessible at http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/orientation_0508_en.pdf

PSI – the pharmacy regulator

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