

Is there any legal and scientific basis for classifying electronic cigarettes as medications?

Journal Article ¹⁾

The rapid growth in the use of electronic cigarettes has been accompanied by substantial discussions by governments, international organisations, consumers and public health experts about how they might be regulated.

In the European Union they are currently regulated under consumer legislation but new legislation will regulate them under the Tobacco Products Directive. However, several countries have sought to regulate them under medicines regulations. These claims have been successfully challenged in 6 court cases in European states. Under European legislation a product may be deemed to be a medicine by function if it is used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. It is a medicine by presentation if it is presented (eg by a manufacturer or distributor) as having properties for treating or preventing disease in human beings.

We assess the legal and scientific basis for the claim that electronic cigarettes should be regulated as medicines.

We conclude that they are neither medicine by function nor necessarily by presentation. The main reason for their existence is as a harm reduction product in which the liking for and/or dependence on nicotine is maintained, and adoption of use is as a substitute for smoking and not as a smoking cessation product.

In reality, they are used as consumer products providing pleasure to the user. They are not used to treat nicotine addiction or other disease, but to enable continued use of nicotine. Their use is adjusted individually by each consumer according to his or her perceived pleasure and satisfaction. Gaps in current regulation regarding safety and quality can be met by tailored regulations.

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