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Commentary

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

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ABSTRACT

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 (e.g. 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.

Introduction

Electronic cigarettes have been gaining in popularity in recent years. First introduced into many counties around 2006, there has been a rapid rise in sales: in the US for example sales were valued at $20m US in 2009, and have more than doubled each year to over $1b in 2013 (Natalie Robehmed, 2013). According to Eurobarometer data from 2012, it is estimated that there are seven millions users in Europe (European Commission, 2012a). They can be considered tobacco harm reduction products, in that they provide an alternative less harmful product to tobacco cigarettes (Rodu, 2011). As in any other kind of harm reduction approach, tobacco harm reduction is appropriate for smokers who want to give up smoking but find it hard to give up nicotine due to the limited efficacy and appeal of currently approved therapeutic options to treat nicotine and cigarette dependence. Moreover, there is a substantial proportion of smokers who are unwilling to be deprived of the positive experience of nicotine or the act of using cigarettes but would prefer an alternative product to maintain perceived pleasure but reduce harm (Bell, 2013; Britton & Edwards, 2008).

Current medications consist of nicotine replacement therapies (NRT – mostly in the form of gums and patches), oral medications (bupropion and varenicline) and psychological support. The efficacy of these medicinal products is disappointing. In randomized controlled trials, NRTs have a 1-year success rate of approximately 7%, which is much less when psychological support is not included (Moore et al., 2009). In cohort studies of real world quit attempts over-the-counter use NRT in self-initiated quit attempts confers no advantage over stopping without any aid (Kotz, Brown, & West, 2014). There is no evidence for the effect of NRT at a population level. The efficacy of oral medications is lower than 20% even in well-designed medical studies (Rigotti et al., 2009), while in everyday clinical practice it is considerably lower (Casella, Caponnetto, & Polosa, 2010). Moreover, oral medications are hindered by serious

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adverse neuropsychiatric effects (Hays & Ebbert, 2010). As a result, the majority of smokers are unable to quit smoking with currently available methods. Additionally, those who want to continue experiencing the positive effects of the smoking habit are unlikely to use any kind of medication since these do not substitute the pleasure perceived from smoking.

Electronic cigarettes consist of a lithium battery, an atomizer, and a fluid filled cartridge. There is no tobacco and no combustion. The atomizer comprises of a storage part for liquid, a resistance and a wick. The liquid evaporates when heated, by activating the battery part of the device which delivers electrical current to the resistance. There is a huge variability of electronic cigarette devices: small "first generation" devices which look similar to a tobacco cigarette, second generation devices which do not resemble cigarettes and are filled by the user and third generation devices which incorporate adjustable electronic circuits that affect taste and performance. The liquid in electronic cigarettes contains nicotine, propylene glycol or vegetable glycerin, and flavorings. There is a large choice of electronic cigarette liquids, with a wide range of flavorings and nicotine levels from 0 up to 36 mg/ml (and more in some cases). Electronic cigarettes are used similarly to tobacco cigarettes: the user takes puffs of aerosol (instead of smoke) and exhales visible aerosol (that resembles smoke in appearance). The difference with electronic cigarettes is that, instead of combustion which produces the smoke in tobacco cigarettes, the aerosol (commonly referred to as "vapor") is produced by heating the liquid at 5–10 times lower temperatures compared to tobacco cigarettes (Laugesen, 2009).

The introduction of electronic cigarettes has led to considerable uncertainty as to how the devices and their contents should be regulated. In the European Union they are currently covered by 17 EU directives and regulations covering for example general product safety, packaging and labeling, chemical safety, electrical safety and weights and measures. Under new legislation which will take effect in 2016, they will be regulated under the Tobacco Products Directive. Several governments, including the UK, Sweden, Germany and Greece have proposed that they should be regulated as medical products and devices. Medicinal regulation was proposed in the draft European Tobacco Products Directive (European Commission, 2012b) but this was rejected by the European Parliament in favor of a consumer model of regulation. According to a briefing from the Library of the European Parliament (Library of the European Parliament, 2013), there have been 6 court cases successfully challenging the classification of electronic cigarettes as medicinal products (1 in USA, 1 in Estonia, 1 in the Netherlands and 3 in Germany), and additionally a recent case in Hungary. In all these cases, the court rulings prohibited the regulation of electronic cigarettes as medications.

In this commentary we examine the legal and scientific basis for the claim that they are medicines. The commentary originated in expert testimony by one of the authors (KF) to the Court of the 2nd and 3rd district of Budapest, Hungary. The Hungarian Customs seized nicotine-containing products and subsequently an electronic cigarette vendor was prosecuted for violating laws of medicines policy. The Hungarian court ruling determined that electronic cigarettes cannot be classified as medicines.

Legal perspective

According to Article 1 of the *Directive 2004/27/EC of the European Parliament and of the Council* (31 March 2004), a medicinal product is: (a) any substance or combination of substances which may be 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, or (b) any substance or combination of substances presented as having properties for treating or preventing disease in human beings. The first part defines the medicinal product by *function*, i.e. when the product has specific physiologic functions on the human organism, while the second part defines the medicinal product by *presentation*, i.e. when the product is presented by the manufacturer as having medicinal properties, for example if a manufacturer of a nicotine containing product claims that the product can be used in the treatment of tobacco addiction.

Defining medicinal products by function

The European Union directive makes a very broad and generalized definition of a medicinal product by function. There are many daily activities and products which exert physiological functions. For example, water intake induces significant hormonal and metabolic changes to the human organism, such as interference with the production of aldosterone and anti-diuretic hormone and elevation of urine output by the kidneys. Salt intake has several metabolic and hormonal effects as well as effects in the regulatory system of the volume status and in kidney function. Coffee, other common beverages and energy drinks also have physiological effects on the human body (in fact, some of these products may have effects very similar to smoking). Eating and physical activity have significant physiological effects (such as elevation of heart rate and blood pressure and changes in hormonal status). Smoking tobacco cigarettes or using any other form of tobacco (hookah, chewable tobacco, snus) also has physiological effects on the human body.

In general, every daily activity of humans has significant effects and induces changes to the human organism. It is irrational to accept that physiological alterations in the human body are produced only by medications, since none of the above-mentioned products or activities is medicinal by nature or by definition. Therefore, we suggest that in order for a substance to be considered as medicinal product by function, it should exert physiological effects above or more intense from what is expected from common daily activities and the use of common products. This has been specifically mentioned in the Court of Justice of the European Union in Commission v Germany, stating that: "[. . .] the product concerned, whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83" (Judgment of the Court, 2007).

Nicotine in tobacco and electronic cigarettes

Liquids used in electronic cigarettes may contain nicotine. Nicotine in these products comes from tobacco leaves and is not produced synthetically. Although synthetic production of nicotine is feasible, to the best of our knowledge no companies currently produce nicotine synthetically because it is significantly more expensive than extracting it from tobacco. The chemical molecule of nicotine in electronic cigarette cartridges is identical to the nicotine present in tobacco leaves. The only process that takes place is the removal of impurities and other chemicals present in tobacco leaves, which means that a cleaner form of nicotine is prepared. Additionally, nicotine is present in other plants, such as eggplants (aubergine), cauliflower, tomatoes and potatoes (Domino, Hornbach, & Demana, 1993). This was probably the main reason why a study on 800 people by the Centers for Disease Control (CDC) in the US found that all participants had detectable cotinine levels in their blood, irrespective of their smoking status (Centers for Disease Control and Prevention, 1993). Nicotine present in electronic cigarettes is identical in nature and molecular composition