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ELECTRONIC CIGARETTES: REGULATORY ISSUES AND SAFETY CONCERNS

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ABSTRACT

An electronic cigarette, e-cigarette or personal vaporizer, is a battery-powered device that provides inhaled doses of nicotine or non-nicotine vaporized solution, while no smoke or combustion is actually involved in its operation. The manufacturers often describe their product as an alternative to smoked tobacco products, such as cigarettes, cigars, or pipes. Electronic cigarette can be used indoors where traditional smoking is prohibited and is not subject to the restriction of the use of tobacco products.

On the evidence of many countries, electronic cigarettes are witnessing a significant increase in global distribution and sales. This increase coincides with implementation of Article 8 of the WHO FCTC (*Protection from exposure to tobacco smoke*) that is leading to the introduction of smoke-free environments in many countries. As market penetration of these products continues to rise, policymakers and regulators in many countries have sought guidance from WHO on the scientific evidence base and optimal regulatory approaches to be taken with regard to these products. Today, Macedonia and Serbia have a strong national ban on smoking in all public indoor places, and in some cases on the outer surface, so that the use of electronic cigarettes is becoming popular. In the market, there are different models of electronic cigarettes that are mainly buying and selling online. The aim of this study was to examine the legal status of this product in Macedonia, Serbia and Bosnia and Herzegovina, reasons for the use or ban, and users' opinions of these products.

Key words: electronic cigarettes, nicotine, design, legislative, directive

ЕЛЕКТРОНСКИ ЦИГАРИ: РЕГУЛАТОРНИ ПРАШАЊА И ГРИЖА ЗА БЕЗБЕДНОСТА

Електронската цигара, е-цигара или персонален испарувач е уред напојуван со батерија кој обезбедува вдишување на никотински или безникотински пареи, при што не постои чад или согорување. Производителите најчесто го опишуваат нивниот производ како алтернатива на тутунските производи како што се цигарите, пурите или лулињата. Електронската цигара може да се користи во затворен простор каде што традиционалното пушење е забрането и таа не е предмет на Законот за забрана на користењето на тутунски производи. Според сведоштвата во многу земји, глобалната дистрибуција и продажба на електронските цигари значително се зголемува. Ова зголемување се совпаѓа со спроведувањето на членот 8 од Рамковната конвенција за контрола на тутунот на СЗО (Заштита од изложеност на тутунски чад), со кој се воведуваат непушачки зони во многу земји.

Бидејќи пробивот на пазарот на овие производи продолжува да расте, регулаторните органи во многу земји под водство на СЗО се ангажираа околу создавањето на научна база и оптималните регулаторни мерки што треба да се преземат во однос на ова прашање. Денес, Р. Македонија и Р. Србија имаат донесено строга забрана за пушење на сите јавни затворени места, а во некои случаи и во надворешната средина, така што користењето на електронските цигари станува се поинтересно.. На пазарот постојат различни модели на електронски цигари кои главно се купуваат и продаваат на интернет. Целта на овој труд е да се одреди законскиот статус на електронската цигара во Р. Македонија, Р. Србија и Р. Босна и Херцеговина, причините за да се дозволи нејзината употребата или да се забрани, како и мислења на корисниците на овие производи.

Клучни зборови: електронска цигара, никотин, дизајн, законска регулатива, директиви

INTRODUCTION

Electronic Nicotine Delivery Systems are designed to deliver nicotine to the respiratory system. The term encompasses products that contain tobacco-derived substances, but in which tobacco is not necessary for operation. They are battery powered devices that provide inhaled doses of nicotine by delivering a vaporized propylene glycol/nicotine mixture. In addition to purported nicotine delivery, this vapour also provides a flavour and physical sensation similar to that of inhaled tobacco smoke (1, 2).

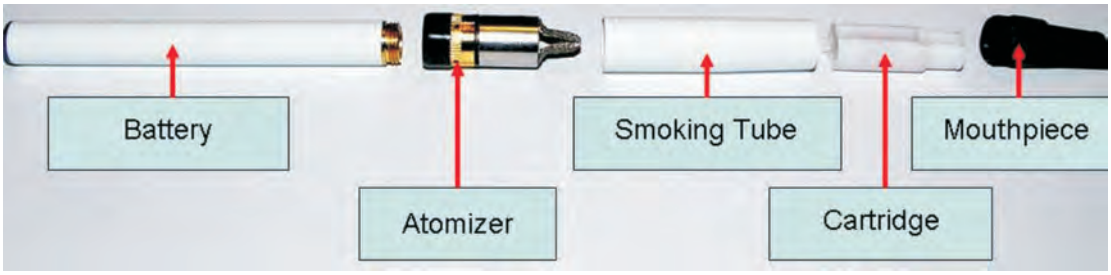
Electronic Nicotine Delivery Systems are marketed under a variety of brand names and descriptors, of which the terms "electronic cigarettes" or "e-cigarettes" are the most common. They are designed to resemble the outward appearance of real smoking products, like cigarettes, cigars, and pipes. Also, they are non-flammable products and there is no danger of burning because it has a light instead of flame. Some products have CE certification and RoHS labelling.

The electronic cigarette was invented by a Chinese medicine practitioner Hon Lik in China in 2003 and introduced to the market the next year. The company he worked for, Golden Dragon Holdings later changed its name to Ruyan (meaning "to resemble smoking") and started selling abroad (3, 4).

In 2006, the electronic cigarette was brought to Europe, and officially launched at the "RUYAN" Overseas Promotion Conference in Austria. After its introduction, this product was adapted to the European market and marketed in UK as the "*electronic cigarette*". According to Electronic Cigarette Association (ECA), the total number of e-cigarette users was estimated to be 300,000 in October 2009, based on survey results (5).

Design and operation

The several existing brands vary but, in general, electronic cigarettes contain: a mouthpiece, a heating element, a rechargeable battery, and various electronic circuits (Picture 1).



Picture 1. Electronic cigarettes component diagram

Battery and electronics

An electronic cigarette battery connected to a USB charger. Most electronic cigarettes employ a lithium-ion rechargeable battery to power the heating element. Battery life varies depending on the battery type and size, frequency of use, and operating environment.

Some electronic cigarettes employ an electronic airflow sensor to automatically activate the heating element upon inhalation, while other models require the user to press a button while inhaling. Various other electronic circuits are usually employed as well, such as a timed cut off switch to prevent overheating and a LED light to signal activation of the device and also to mimic the glow of a cigarette's end tip.

Heating element

The electronic cigarettes closely resemble and purposefully mimic the art of smoking by having users inhale vaporized liquid nicotine created by heat through an electronic ignition system

The heating element serves to vaporize the liquid in the mouthpiece so that it can be inhaled. This component is referred to in the industry as an "atomizer". Atomizers have a finite life of about one month and are one of the recurring expenses associated with electronic cigarettes.

The vapours are expelled via a cartridge that usually contains a concentration of pure nicotine. The cartridge and ignition system are housed in a device created to look exactly like a traditional cigarette, cigar or pipe.

Mouthpiece

The mouthpiece is a small disposable plastic cup-like piece affixed to the end of the tube. Inside the mouthpiece is a smaller plastic cup which holds an absorbent material that is saturated with a flavoured liquid solution that may contain nicotine. This inner cup is made such that air is able to flow around it and through a hole in the end of the outer piece; this is necessary for the device to provide the ability for suction to move the vapour into the user's mouth. The mouthpiece is referred to in the industry as a "cartridge". Nicotine is delivered through replaceable cartridges that are available in various concentrations (e.g. 16 mg, 11 mg, 6 mg and 0 mg). Thus, the device can be adjusted to various levels of nicotine as per the needs of the user. When the liquid in the cartridge has been depleted, it can either be refilled by the user or replaced with another pre-filled cartridge.

Another type of cartridges is those in which nicotinic solution is directly added in drip tips. By removing the absorbent material, one is able to simply remove the plastic mouthpiece and drip several drops of e-liquid directly onto the atomizer bridge. To further ease dripping, some manufacturers have created specialty mouthpieces made of stainless steel or plastic that are intended just for dripping and do not require removal each time you drip.

Nicotine and non-nicotine solution

Nicotine solutions sold separately for use in refillable cartridges are sometimes referred to as "e-liquid" or "e-juice", and commonly contain some amount of flavouring, with hundreds of different flavours available. They consist of nicotine dissolved in propylene glycol (PG) and/or vegetable glycerine (glycerol) or VG (). Solutions are also available in differing nicotine concentrations, to let the user decide the amount of nicotine to be taken in. Concentrations range from Zero Nicotine, low and midrange doses (6–8 mg/ml and 10–14 mg/ml respectively), to high and extra-high doses (16–18 mg/ml and 20–54 mg/ml respectively). Solutions are also available that contain no nicotine at all (6).

Some commercial e-liquids trying to resemble a regular or specific cigarette brands like Marlboro or Camel, and cigarettes with flavour (menthol, vanilla, caramel, chocolate and coffee).

A liquid formulation used in electronic cigarettes was tested by gas chromatography mass spectrometry (GC-MS) to identify the major ingredients in the mixture and their relative concentrations. The composition of some commercially available tobacco liquids are presented in Table 1 (4, 7).

Table 1. Composition of some commercially available tobacco liquids

Substance	Recipe 1	Recipe 2	Recipe 3	Recipe 4	Recipe 5
Propylene glycol	85%	80%	90%	80%	<65%
Nicotine	1.6%	2.4%	3.2%	0.1%	<3%
Glycerol	2%	5%	-	5%	<20%
Tobacco essence	-	4%	4.5%	1%	<5%
Essence	2%	-	1%	1%	<5%
Organic acid	1%	-	-	2%	<1%
Anti-oxidation agent	1%	-	-	-	-
Butyl valerate	-	1%	-	-	-
Isopentyl hexonate	-	1%	-	-	-
Lauryl laurate	-	0.6%	-	-	-
Benzyl benzoate	-	0.4%	-	-	-
Methyl octynicate	-	0–5%	-	-	-
Ethyl heptylate	-	0.2%	-	-	-
Hexyl hexanoate	-	0.3%	-	-	-
Geranyl butyrate	-	2%	-	-	-
Menthol	-	0.5%	-	-	-
Citric acid	-	0.5%	2.5%	-	-
Water	-	-	-	2.9%	<10%
Alcohol	-	-	-	8%	-
2,3,5-Trimethylpyrazine	-	-	-	-	<1%
2,3,5,6- Tetramethylpyrazine	-	-	-	-	<1%
2,3-Dimethylpyrazine	-	-	-	-	<1%
Acetylpyrazine	-	-	-	-	<1%
Terpineol	-	-	-	-	<1%
Ethyl maltol	-	-	-	-	<1%
Guaiacol	-	-	-	-	<1%
Acetylpyridine	-	-	-	-	<1%
Octalactone	-	-	-	-	<1%

Legislative requirements

Many world public health authorities caution that the risks and benefits of Electronic Nicotine Delivery Systems (ENDS) have not been adequately studied, that they may not deliver nicotine as claimed and may deliver more toxicants than claimed.

There is also concern that they may undermine smoking prevention, cessation and clean air laws (8, 9). Some countries have banned ENDS until they are adequately studied (e.g. Brazil, Canada, Uruguay, Singapore, Turkey) (9).

Because of the relative novelty of the technology and the possible relationship to tobacco laws and medical drug policies, electronic cigarette legislation and public health investigations are currently pending in many European countries.

In Denmark, the Danish Medicines Agency classifies electronic cigarettes containing nicotine as medicinal products. Thus, authorization is required from the retailer before the product may be marketed and sold (10).

In Finland, the sale of electronic cigarette is banned and it is considered as a medical device instead of a nicotine therapy product.

In Netherlands, use and sale of electronic cigarettes is allowed, but advertising is forbidden pending European Union legislation (11).

In Norway the Directorate of Health prohibits import and sale of electronic cigarettes, based on this being considered a medical product due to its nicotine content. However, obtaining electronic cigarettes for personal use is permitted from any country within the European Economic Area.

In the United Kingdom, use and sale of electronic cigarettes is currently unrestricted, although the MHRA has proposed bringing all nicotine products except tobacco within the medicines licensing regime (12).

In Italy, use and sales of electronic cigarettes is permitted but all products containing Nicotine must be labelled with hazardous symbols as per Directive 2001/95/CE and 1999/45/CE.

In Greece, the recent law on protection from tobacco and alcohol bans the marketing of e-cigarettes unless a Ministerial decision authorises them under certain conditions.

Regulators of medical and tobacco products should collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating the electronic cigarettes to protect public health.

Under the Tobacco Products Directive (2001/37/EC) 'tobacco products' means "products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not" (13).

Electronic cigarettes may fall under the Tobacco Products Directive only if they contain tobacco (even a marginal amount is enough). However, these kinds of products have the potential of undermining the smoking cessation policies, since they keep the smoking addiction.

Conclusion: Electronic cigarette not containing tobacco is not a tobacco product under the Tobacco Products Directive (2001/37 EC).

Article 1(2) of Pharmaceutical Products Directive (2001/83/EC) gives the following definition of a medicinal product (14):

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) 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.

The electronic cigarette is normally a device whose only purpose is to administer nicotine into the human body through inhalation. The manufacturers often describe their product as an alternative cigarette and marketing may also refer to use as cessation aid.

Nicotine is a substance that has a strong effect on central nervous system and it causes strong physical addiction and withdrawal symptoms.

It is for each national authority to decide, account being taken of all the characteristics of the product, whether it falls within the definition of a medicinal product by its function or presentation.

Conclusion: Whether the electronic cigarette falls under Directive 2001/83/EC on human medicinal products depends on whether it can be characterised as human medicine by presentation (as a remedy to get rid of nicotine addiction) or by function (as it qualifies as "restoring, correcting or modifying physiological functions").

Article 1 (2) a of Medical Devices Directive (93/42/EEC) requires that, in order for a product to be qualified as a medical device, it is to have a medical purpose.

Manufacturer of electronic cigarettes should declare whether their products will be used for medical purposes or not.

Conclusion: Whether the electronic cigarette could be regarded as falling under Directive 93/42/EEC on medical devices depends on the claimed intended use and whether this intended use has a medical purpose or not.

Electronic cigarettes are consumer products and their safety risk assessment (and management) can in theory fall under the General Product Safety Directive 2001/95/EC to the extent they are not covered by other Community legislation setting forth more specific provisions with the same objective (15).

Conclusion: The Directive 2001/95 on general product safety applies in so far as there are no specific provisions with the same objective in other Community law. This Directive enables the withdrawal of the product from the market if the regulator can show that it is dangerous to the health and safety of consumers.

Summary of all requirements of mentioned EC legislatives for electronic cigarettes is presented in Table 2.

Table 2. Requirements of EC legislatives for electronic cigarettes

Directive	Prior authorisation	Safety tests	Advertising restrictions	Other requirements
Tobacco Products (Directive 2001/37)	No	No	Yes	Warning labelling, Ingredients reporting
Pharmaceutical Products (Directive 2001/83)	Yes	Yes	Yes	Effectiveness tests
Medical Devices (Directive 1993/42)	No		No	Conformity assessement, CE marking
General Product Safety (Directive 2001/95)	No	Yes	No	

The health effects of using electronic cigarettes

Electronic cigarettes are probably less harmful than cigarette smoking, but they can't be recommending as a permanent replacement or alternative to smoking.

However, to our knowledge, there is no published research data on the safety of electronic cigarettes and the health effects of using electronic cigarettes are currently unknown (16, 17).

It has published two reviewed studies of electronic cigarettes nicotine delivery in humans and provides preliminary data on nicotine absorption and craving relief by several products (18, 19). Two limitations of the studies are worthy of special note. First, there are hundreds of brands and models of electronic cigarettes, with diverse claims implying unique modes of operation, contents and widely varying nicotine, suggesting potential differences from those tested to date. Second, these short term laboratory studies offer little basis for assessing the safety of electronic cigarettes as they would actually be used, which could involve hundreds of puffs per day for many years with puffing parameters varying widely.

To date, there is no research to support the manufacturers' claims that electronic cigarettes help smokers quit, the World Health Organization proclaimed that it does not consider the electronic cigarette to be a legitimate smoking cessation aid (16).

If they claimed that they help smokers quit, manufacturers would be subject to the legislation and regulation that applies to Nicotine replacement therapy NRT products. In order to avoid this, some electronic cigarettes are now marketed for enjoyment, or as devices that enable smokers to "smoke" everywhere, including smoke free places. Nonetheless, some distributors present their products as an alternative to tobacco smoking, more or less implicitly suggesting that e-cigarettes can be used to aid smoking cessation.

Analyses conducted by the United States Food and Drug Administration (FDA) showed that electronic cigarettes contained detectable levels of known carcinogens and other toxic chemicals. The FDA also found that cartridges labelled as containing no nicotine did in fact contain low levels of nicotine (20).

The judicial ruling preventing the FDA from banning electronic cigarettes imports will complicate its efforts to regulate the products; however, the FDA has several regulatory avenues, in addition to its new authority to regulate tobacco products (21).

DISCUSSION

The presence of e-cigarettes on the Internet, including in Web searches, virtual user communities, and online stores where people sell e-cigarettes on commission, is increasing rapidly.

The legal status of the electronic cigarette is unclear in many countries, and its regulation is complex; it is neither classed as a tobacco product, nor food, nor is it registered as a medicine.

From a public health perspective, however, the question is whether - at a population level - the potential benefits of the electronic cigarette outweigh its drawbacks. There is a difficult balance between the need to protect consumers and the possibility now being offered to smokers to use a new, acceptable and potentially effective device to stop smoking. However, the electronic cigarette is not defined as a tobacco product by any law on tobacco and tobacco products.

Now it is still early to make judgments about the presence of electronic cigarettes in the Balkan region, because the electronic cigarettes are mainly bought and sold online and by retailers.

Electronic cigarettes are mainly marketed to current smokers either for enjoyment or for use in smoke-free places and to people who use them to help quit smoking. There are no official data relating to the consumers opinion for this product.

For these reasons, for now it is not possible to do an official study on the use of electronic cigarettes.

From the sites relating to the electronic cigarette can be concluded that most people who buy this product are current and former smokers. They are devoting more positive than negative effects from this product like effects on the respiratory system (breathing better, coughing less), which were probably associated with stopping smoking. The fact that electronic cigarette can be used indoors where traditional smoking is prohibited and do not produce any unpleasant odours or environmental tobacco smoke was also appreciated.

One may hypothesize that the positive effects of electronic cigarettes may include smoking cessation, smoking reduction or relapse prevention. The electronic cigarettes could also be used as an aid during a preparation period before cessation, similar to the pre-cessation treatment or "cut down to quit" approach that is an approved indication for Nicotine replacement therapy (NRT).

A large proportion of buyers are people who use them to help quit smoking. But, they may also enable smokers to continue to 'smoke' in smoke-free environments, thus delaying or preventing cessation in people who might otherwise quit. Finally, because of its rapid nicotine delivery, they also have the potential to be addictive.

Many users were concerned about the safety and toxicity of electronic cigarettes, and questioned why no study has yet investigated these aspects.

The health effects of using electronic cigarettes are currently unknown. Several studies regarding the long-term health effects of inhaling nicotine vapour are currently in progress.

Electronic cigarettes may be dangerous because of the frequent and long term lung inhalation of nicotine, propylene glycol and other toxic components. Some manufacturers claim that the content of nicotine is many times lower than that of a classic cigarette.

On the other hand, one cartridge may include different intensities of nicotine content, for example 0 mg, 6 mg, 11 mg or 16 mg of nicotine according to user's choice. One cartridge is said to correspond to 15-20 cigarettes.

This means that the electronic cigarette - with the most intense cartridge - gives about the same yield of nicotine as one cigarette (1 mg). Therefore, the statement that the product contains "many times lower," nicotine from cigarettes mislead consumers.

Furthermore, some of electronic cigarettes are not manufactured according to the high standards imposed on pharmaceutical companies and inhaled vapour may contain impurities that may be dangerous to consumers. In particular, the origin of the nicotine itself is uncertain, as pesticide-grade nicotine rather than pharmacological grade nicotine may be used in electronic cigarettes.

Finally, the fruit and chocolate flavours may appeal to young people, and this raises the concern that electronic cigarettes may facilitate initiation of nicotine dependence in young never-smokers.

Laws banning smoking, which are in effect starting this year in Macedonia and Serbia prohibits the use of tobacco products.

In Bosnia and Herzegovina, for ten years, there is the Law on restricted use of tobacco products, which also does not allow smoking in public places and advertising of tobacco products, but it is not implemented in practice.

More than 170 countries adopted in November 2010 at the conference of the World Health Organization (WHO) in Uruguay measures to strengthen the fight against tobacco, including those related to adding flavors in cigarettes.

The Parties to the Framework Convention on Tobacco Control, which also include Macedonia, Serbia and Bosnia and Herzegovina, have reached an agreement on the introduction of assistance programs for smoking cessation in national health systems and support campaigns to raise awareness of the population, according to a WHO statement.

Participants are not taken any decision regarding the control of "electronic cigarettes" and similar products containing tobacco. On this subject will be discussed at the next meeting 2012th in South Korea.

CONCLUSIONS

The electronic cigarettes are new, untested and unregulated high-tech nicotine-smoking devices, which have recently been made available to all consumers. Electronic cigarettes are used mainly on places where traditional smoking is prohibited. These products are buying by people who use them to help quit smoking and may be useful for this purpose. Almost all users were concerned about the potential toxicity of these devices. Very few studies have investigated efficacy and toxicity of electronic cigarettes and research is now urgently required.

When determining if a product is safe, the Regulations require further consideration of:

1. The characteristics of the product: the electronic cigarettes are required to be composed well, easy to use and contain instructions for assembly and usage. Notably, the refill cartridges need to be in child resistant safety packaging.

2. The effect of the product: there is presently no scientific evidence to confirm the product's safety and efficacy. It is not known what effects the nicotine has with the other chemicals contained in the cartridge refills which cause the vapour to excrete from the product. This could be potentially dangerous to users.

3. The presentation of the product: the product needs to be adequately labelled in terms of the manufacturers (and importers) details, its contents etc. Products containing high levels of nicotine solution are legally required to display the 'Highly Toxic' warning.

4. What will need to be regulated by law is a ban on selling electronic cigarettes to persons less than 18 years, given that this product contains nicotine, which creates a dependency on e-smoking.

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