Electronic cigarettes

SUMMARY *Electronic cigarettes (e-cigarettes) work by vaporising nicotine liquid. They are aimed at people who do not want to smoke tobacco but cannot or do not want to overcome their nicotine addiction.*

They are mostly produced in China, and marketed in Europe by small and medium-sized firms. The market is growing rapidly.

The variety of products on the market makes it hard to assess their safety, but the available evidence suggests that they are much less harmful than tobacco cigarettes. E-cigarettes show some promise for reducing the consumption of tobacco.

They are regulated differently in the Member States: as tobacco products or pharmaceutical products or as consumer products under the General Product Safety Directive.

The European Commission proposed regulating them as medicinal products in its revision of the Tobacco Products Directive. The e-cigarette industry prefers regulation as either consumer products or tobacco products.

Proponents of e-cigarettes argue that they reduce harm to smokers and their environment by delivering nicotine without the harmful effects of tobacco smoke. Opponents warn of harmful substances in e-cigarettes, and point out they can lead to nicotine addiction.

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Electronic cigarettes with battery charger

In this briefing:

Glossary

Denormalisation: making behaviour unacceptable by changing social, environmental and cultural norms and perceptions.

Harm reduction: policies focused on reducing the harm associated with a behaviour (rather than preventing the behaviour) in people unable or unwilling to stop (for example needle exchange programmes for heroin addicts).

Vaper: consumers of electronic cigarettes refer to themselves as 'vapers' and not as smokers, because they inhale vapour, not tobacco smoke.

What are electronic cigarettes?

E-cigarettes[1] work by vaporising nicotine liquid. They consist of a battery, a cartridge (containing an 'e-liquid' that typically consists of propylene glycol, nicotine and flavourings), and an atomiser which heats the cartridge ingredients to create a vapour that is inhaled by the consumer ('vaper'). They do not contain tobacco and there is no combustion, no smoke and no odour.

Many e-cigarettes look like cigarettes, but other shapes are available. E-cigarettes are used like cigarettes: when the user draws on an e-cigarette, visible vapour is produced and an LED may light up to mimic the glow of a real cigarette. Vapers report that the sensation ('nicotine hit') is similar to that of using tobacco cigarettes.

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E-liquids contain nicotine concentrations between 0 and 48 mg/ml, typically 18 mg/ml. More than 200 flavours are available.

While the initial costs for the equipment are rather high (around €30 to 80), the recurring costs for e-liquids are generally much lower than the cost of cigarette smoking (due to the absence of excise duty) or of nicotine replacement therapies.

E-cigarettes vs. nicotine replacement therapies

The proposed revision of the Tobacco Products Directive (2012) considers most e-cigarettes as medicinal products, subject to the same regulation as nicotine replacement therapies (NRT). While both types of products deliver nicotine without tobacco smoke, they differ in various aspects:

NRT	electronic cigarette
marketed as cessation aid	marketed as replacement for tobacco cigarette
marketed to health professionals and consumers	marketed to consumers
slow nicotine delivery, low risk of addiction	nicotine 'hit', high risk of addiction
controlled dosage of nicotine	consumer controls the dosage
unattractive by design to avoid 'abuse-liability'	considered attractive, and used in social situations
standardised product with long innovation cycles	wide variety of shapes and flavours, rapid innovation cycles
sold in drugstores and pharmacies	sold through various retail channels and over the internet
subject to clinical trials and approval	subject to product safety legislation (except where regulated as tobacco products or medicines)
claims of efficacy for smoking cessation	no health-related claims are made
produced by pharmaceutical companies	produced/marketed mostly by small and medium-sized enterprises

There are five types of NRT: patches, nasal sprays, inhalers, chewing gums and lozenges.

The e-cigarette industry does not make any health claims, in order to clearly differentiate their products from NRT, and to avoid regulation as medicinal products.

Market trends

Market size and industry structure

The market for e-cigarettes is growing rapidly. Industry analysts estimate that the global market for e-cigarettes exceeds €1.5 billion annually, and the EU market is around €400-500 million. In 2010, e-cigarettes and NRTs each had a 0.4% share of the EU tobacco and nicotine market.

The EU market is dominated by small and medium-sized firms acting as distributors. Most e-cigarettes are manufactured in China, where Hon Lik, a pharmacist, patented e-cigarettes in 2003. E-liquids are also produced in the EU. Ingredients are often not published, and there is no mandatory control of safety and quality.

Until recently, the big tobacco companies were not involved in the e-cigarette market. In April 2012, Lorillard bought e-cigarette maker Blu for $135 million. In December 2012, BAT acquired CN Creative Ltd, a UK company that develops e-cigarette technologies. RJ Reynolds is developing its own electronic cigarette technology.

Consumers

In a recent Eurobarometer survey (2012), 1% of respondents said they used e-cigarettes.

Currently, they are mostly used by (predominantly male) smokers and ex-smokers, and only rarely by people who have never smoked. However, a survey of over 20 000 Polish students found that one-fifth of them have tried e-cigarettes (most of them had previously smoked cigarettes). A survey among school children in Paris shows that 8% have tried e-cigarettes, and indicates that e-cigarettes could be used as an

initiation to nicotine consumption. Falling prices, attractive products, peer pressure and a lack of age limits may contribute to increased use among young people.

The e-cigarette industry is careful not to market to non-smokers and minors, and industry representative ECITA advocates prohibiting sales to minors.

The scientific evidence

"People smoke for nicotine but they die from the tar." Professor Michael Russell, 1976

Health risks of e-cigarette vapour

While the dangers of smoking and of environmental ('second-hand') tobacco smoke are well established, there is no consensus about the health impacts of e-cigarette vapour. Medical researchers and public health agencies note that not enough knowledge is available to establish the safety of e-cigarettes or their long-term effects (and indeed the variety of products on the market makes it hard to arrive at general conclusions). They point out that nicotine is toxic and addictive. Therefore they generally do not recommend consuming electronic cigarettes and some even propose prohibiting their use in smoke-free areas.[2]

Propylene glycol

Propylene glycol, classified as "generally recognised as safe" by the Food and Drug Administration, is used in food, cosmetics, pharmaceutical products, and also in artificial smoke for fire safety training, theatrical performances, and rock concerts. It is a main component of e-liquids.

A review of 16 studies concludes that "few, if any, chemicals at levels detected in electronic cigarettes raise serious health concerns" and that e-cigarettes are comparable in toxicity to NRTs and much less harmful than tobacco cigarettes. In 2009, a study by the US Food and Drugs Administration (FDA) found dangerous substances "at very low levels". A recent laboratory study shows that levels of toxic substances in e-cigarette vapour are 9–450 times lower than in cigarette smoke and, in many cases, comparable with trace amounts found in medicinal nicotine inhalers.

Research shows that e-cigarette use causes harmful short-term increased airway resistance in the lungs. There are no studies of long-term effects on humans.

E-cigarette use releases substances into the environmental air, but there is no evidence that these are dangerous. Flavourings may also pose a health risk.

Product quality and safety

As reported by the European Commission (EC) impact assessment, in some cases the nicotine content of the liquids differs from the declaration on the packaging. Traces of nicotine were found in products labelled as nicotine-free.

There is also a serious risk of nicotine poisoning in case of leaking cartridges or bottles which are not child-proof.

Effectiveness

In considering the effectiveness of e-cigarettes and NRT, whether the longer-term objective is to stop smoking tobacco (smoking cessation) or to stop using nicotine altogether (nicotine cessation) must be determined. Studies of the effectiveness of NRTs measure combined smoking/nicotine cessation rates, while studies of e-cigarettes generally report only smoking cessation rates.

Although clinical studies find NRTs moderately effective, a recent long-term empirical study found NRTs were not more effective than quitting without NRT.

A survey of 222 vapers found that 31% did not smoke six months after purchasing their first electronic cigarette, and two thirds had reduced their cigarette consumption. The nicotine cessation rate was 10.6% after six months. Another survey found the majority of vapers fear that they might go back to smoking if they could not use e-cigarettes. 82% of surveyed Polish vapers thought e-

cigarettes were less dangerous than tobacco cigarettes, but not completely safe.

Consumer attitudes and behaviour

Users' attitudes influence whether or not they are willing to use products like e-cigarettes or NRT. A recent qualitative study found that:

- e-cigarettes, which deliver nicotine and can be used like cigarettes, address both biochemical and behavioural aspects (hand-to-mouth movement) of smoking addiction,
- vapers derive social benefits from online forums and vaping clubs, and may even treat vaping as a hobby,
- being a 'vaper' becomes part of the personal identity that replaces the previous 'smoker' identity,
- users can quit smoking without giving up nicotine.

The International Tobacco Control Four-Country Survey (nearly 6 000 respondents from Australia, Canada, UK and US) found that 47% were aware of e-cigarettes and 7.5% had tried them. 85% of users use e-cigarettes to help quit smoking.

A face-to-face survey of 104 experienced vapers found that some use e-cigarettes as tobacco substitute over a long term.

Regulation of e-cigarettes

Current situation

Member States take different approaches (see Annex) to the regulation of e-cigarettes:

- complete prohibition
- as tobacco products
- as medicinal products
- as consumer products

Nicotine

Jean Nicot (1530-1600), after whom nicotine is named, introduced tobacco as a medicine to the French court.

Nicotine activates neurons in the brain and increases the release of neurotransmitters. It increases blood pressure and heart rate, and acts as a stimulant and relaxant. Studies have found that nicotine has beneficial effects on motor abilities, attention, and memory.

According to the Royal College of Physicians, nicotine addiction depends on a number of factors, including the nicotine delivery mechanism. While medicinal nicotine products are designed to minimise their addiction potential, cigarettes are designed and marketed to be the most addictive nicotine product.

While nicotine is toxic in high doses (the tobacco plant uses it as a natural insecticide), the Royal College of Physicians considers medicinal nicotine as a very safe drug, "no more harmful than the existing use of caffeine". The nicotine used in e-cigarettes and NRT is extracted from the tobacco plant.

Some Member States are in the process of revising their approach:

The UK medicines regulator MHRA is investigating the best way to regulate e-cigarettes without driving users back to smoking cigarettes.[3] A decision is expected in spring 2013.

A study on the regulation of e-cigarettes for the French health ministry is to be published in May 2013.

European Parliament

EP and Council will decide on the Commission's proposal for a revision of the Tobacco Products Directive (which chooses to regulate e-cigarettes as medicinal products) under the ordinary legislative procedure. The EP's Environment Committee nominated Linda McAvan (S&D, UK) as rapporteur.

On 19 March 2013, the Committee had meetings with representatives of the tobacco and e-cigarette industries.

Regulatory approaches

Prohibition

Greece prohibits e-cigarettes (unless specifically approved by the Health Ministry). Lithuania bans electronic cigarettes as imitation tobacco products.

Arguments in favour of prohibition of e-cigarettes are that their safety is not proven, they can cause nicotine addiction and provide a 'gateway' to smoking.

Opponents consider prohibition as a "smoke or die" approach that will drive nicotine addicts to smoking tobacco products. It may also lead to the emergence of a black market for e-cigarettes and e-liquids without any quality controls.

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Regulation as tobacco products
Malta regulates e-cigarettes as tobacco products.

Regulation of e-cigarettes as tobacco products creates a level playing field between tobacco companies and manufacturers of e-cigarettes while leading to differential treatment of e-cigarettes and NRT. However, subjecting e-cigarettes to tobacco control measures does not take into account their potential for harm reduction.

Regulation as medicinal products
Fourteen Member States (see Annex) regard at least some electronic cigarettes or e-liquids as 'medicinal products by function'.

Regulation as medicinal products puts e-cigarettes and NRT on an equal footing, but leads to differential treatment between tobacco products and e-cigarettes. The Commission's impact assessment argues that regulating e-cigarettes as medicinal products would increase their safety, while the e-cigarette industry claims that regulation as consumer products is stricter when it comes to warning labels or child-proof packaging. Sold as a medicinal product, e-cigarettes would be less accessible to non-smokers, but also less attractive to tobacco smokers who do not consider smoking as a disease[4] requiring medical treatment.

Obtaining a marketing authorisation for a medicinal product is costly and slow. An e-cigarette company estimates that the total cost exceeds €200 000. ECITA reports of a company that has spent more than €2 million on an authorisation process, but still not received the marketing authorisation after three years. The e-cigarette industry fears that the long approval process may lead to impaired technological development and product innovation: medicinal e-cigarettes may become less attractive to smokers, with less appealing packaging (to avoid abuse for non-medical purposes) and a more limited choice of flavours.

The EC's impact assessment considers e-cigarettes should be treated as 'medicinal products by function', because they contain nicotine, a substance with pharmacological effects. Its proposal for the revision of the Tobacco Products Directive therefore places e-cigarettes containing more than 4mg/ml of nicotine (applying to most e-cigarettes on the market today) under the Human Medicinal Products Directive (2001/83/EC).

Regulation as consumer products
In nine Member States (see Annex), with no specific rules, e-cigarettes are subject to existing product safety legislation. Poland prohibits advertising for e-cigarettes.

The e-cigarette industry argues that e-cigarettes should be regulated as consumer products, since they are neither tobacco products nor medicinal products intended to cure nicotine addiction. They argue that the existing legislation (General Product Safety Directive 2001/95/EC) is sufficiently strict and that the RAPEX alert system is suitable for removing dangerous products from the market quickly.[5] Regulation as consumer products enables manufacturers to make e-cigarettes attractive through design, packaging and promotion. This can contribute to harm reduction if it entices smokers to switch to e-cigarettes, but could also tempt young people to start consuming nicotine. The WHO Framework Convention on Tobacco Control (FTCT) warns that e-cigarettes which resemble cigarettes may undermine efforts to 'denormalise' tobacco.

While consumer product safety legislation is quite comprehensive, it is not systematically enforced. Stronger enforcement by the authorities and self-regulation by industry[6] are suggested as means to ensure the safety of e-cigarettes and e-liquids.

Anti-tobacco campaigner Clive Bates advocates regulating e-cigarettes as a consumer product, complemented by some rules to take account of the specificities of electronic cigarettes.

Regulation as a separate product category
Michael Siegel, an American tobacco-control expert, proposes a specific regulatory frame-

work for e-cigarettes under which companies and products would be registered with the competent authority, all ingredients would be declared, and the purity and safety of products would have to be demonstrated.

Case law

Classification of e-cigarettes as medicinal products has been challenged in the courts.

The Tartu Administrative Court (Estonia) ruled in March 2013 that e-cigarettes are not medicinal products since they are comparable to tobacco cigarettes in that they satisfy nicotine addiction rather than cure it.

The 's-Gravenhage Court (the Netherlands) ruled in March 2012 that e-cigarettes do not fall under medicinal-products legislation.

In Germany, the Cologne Administrative Court and the Sachsen-Anhalt Higher Administrative Court (OVG) concluded in 2012 that e-cigarettes and e-liquids are not medicinal products. The Nordrhein-Westfalen OVG prohibited the health minister from stating that e-cigarettes and e-liquids must be authorised as medicinal products.

In 2010, the US Court of Appeals prohibited the Food and Drugs Administration (FDA) from regulating e-cigarettes as medicinal products if they are not marketed for therapeutic purposes. Following the ruling, the FDA intends to regulate e-cigarettes as tobacco products.

In cases concerning food supplements and garlic preparations, the Court of Justice of the EU ruled that the Human Medicinal Products Directive can only be applied to a product which has been scientifically established to be a 'medicinal product by function'.

Expert and stakeholder positions

NGOs

Action on smoking and health (ASH) argues that e-cigarettes contribute to harm reduction and should be made available, provided that they are properly regulated to ensure safety and efficacy.

Health sector

The WHO Study Group on Tobacco Product Regulation proposes that e-cigarettes be regulated as nicotine delivery devices (preferably), or under tobacco control laws.

The fifth Conference of the Parties to the FTCT in November 2012 called for more research on health impact and best practices, and for the identification of policy options for the control of smokeless tobacco and electronic nicotine delivery systems.

The European Respiratory Society opposes electronic cigarettes and advises smokers to quit completely.

The Royal College of Physicians advocates a 'harm reduction' approach and considers it a moral and ethical duty to provide safer sources of nicotine to addicted smokers.

Bertrand Dautzenberg, president of the Office français de prévention du tabagisme, advocates regulating e-cigarettes as medicines to prevent them from becoming a product for initiation and indirect promotion of tobacco consumption.

Industry

UK-based ECITA, representing 21 e-cigarette companies, favours applying regulation of consumer products to e-cigarettes, industry self-regulation, better enforcement of existing regulations and a ban on marketing and sales to minors. ECITA maintains that consumers should have a choice between harmful cigarettes and less harmful alternatives.

The Tobacco Vapour Electronic Cigarettes Association (TVECA), representing 13 European e-cigarette companies, proposes regulation as a tobacco product, taking into account the specific characteristics of e-cigarettes.

The pharmaceutical industry is in favour of regulating e-cigarettes as medicinal products. Novartis, a pharmaceutical company, is lobbying for increased

availability of NRT as an important component of an EU tobacco control strategy.

Consumers

German consumer group IG-ED proposes treating e-cigarettes as consumer products, and considers the nicotine threshold in the Commission proposal as arbitrary and protective of the interests of the NRT industry.

E-cigarette consumer associations in various EU countries have encouraged vapers to contact their MEPs and make the case for regulating e-cigarettes as consumer products. More than 40 000 people have signed online petitions addressed to the European Commission and to the EP's President urging the treatment of e-cigarettes as consumer products.

Main references

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Electronic nicotine delivery systems, including electronic cigarettes: Report by the Convention Secretariat, WHO Framework Convention on Tobacco Control, 2012
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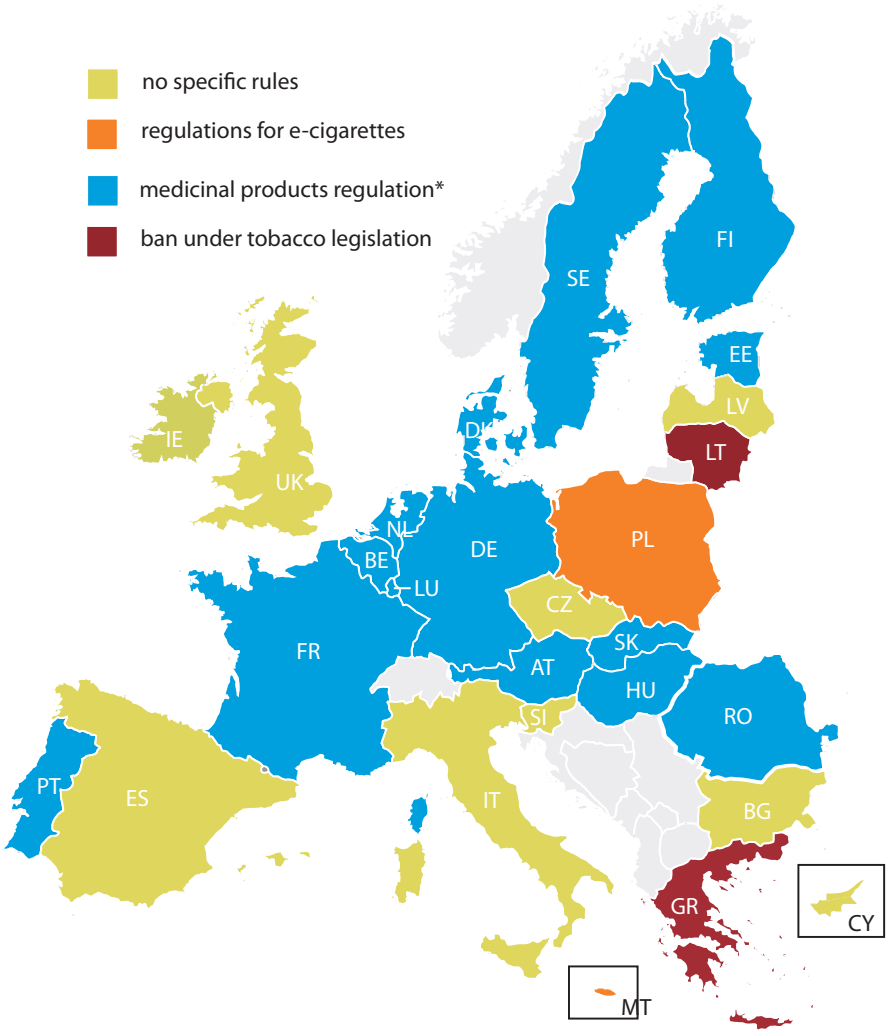
Annex: Regulation in EU Member States

Bulgaria, Cyprus, Czech Republic, Ireland, Italy, Latvia, Slovenia, Spain, United Kingdom	no specific rules, existing consumer product safety legislation applies
Belgium, Luxembourg	considered as tobacco product if it contains tobacco extract, and as medicinal product if it contains nicotine but no tobacco extract
Austria, Denmark, Estonia, Finland, Germany, Hungary, Netherlands, Portugal[7], Romania, Slovakia, Sweden	considered as medicinal product; Finland bans advertising
France	considered as medicinal product if nicotine content exceeds limits (10mg or 20 mg/ml)
Greece	prohibited unless specifically approved by Health Ministry.
Lithuania	banned as imitation tobacco products, regardless of nicotine content
Malta	regulated under tobacco act
Poland	advertising ban

Belgium, Malta and Slovakia ban the consumption of electronic cigarettes in enclosed public places, bars and restaurants and other workplaces. (source: European Commission, implementation report on smoke-free environments, March 2013).



Regulation of electronic cigarettes in the EU

(data source: European Commission - Annex 3 of impact assessment for the revision of the Tobacco Products Directive)

*MS which considers at least some nicotine-containing products as medicinal products

Endnotes

[1] Electronic cigarettes are also referred to as 'electronic nicotine delivery systems' (ENDS) by the WHO, and categorised as 'nicotine containing products' together with other products such as chewing gum containing nicotine.

[2] British Medical Association, BFR (German federal office for risk assessment), DKFZ (German cancer research centre), French Medicines Safety Agency, Johns Hopkins Health Information Network, World Health Organisation.

[3] Several UK agencies advocate access to safer nicotine products as part of a harm reduction approach: the UK Department of Health supports "new approaches to encourage tobacco users who cannot quit to switch to safer sources of nicotine"; the UK Government's Behavioural Insights Team encourages the development of safe nicotine products which offer an attractive alternative to cigarettes; NICE, the National Institute of Health and Clinical Excellence, has published draft guidance which states that e-cigarettes are " likely to be less harmful than cigarettes" although " their safety and quality can't be assured".

[4] In 1980, the American Psychiatric Association proclaimed tobacco addiction to be a psychiatric condition. In 1988, the U.S. Surgeon General declared smoking to be an addiction. In 1993, the World Health Organisation (WHO) included tobacco use as a mental and behavioural disorder in the tenth revision of the International Classification of Diseases (ICD-10).

[5] RAPEX notifications concerned the electrical safety of e-cigarettes (batteries and chargers) and missing or inadequate warning labels on e-liquids. In the US, an exploding e-cigarette injured one person, but explosion incidents have also been reported with the batteries of laptops and mobile phones.

[6] ECITA has developed an 'Industry Standard of Excellence', based on EU legislation.

[7] Considered as medicinal product only when explicitly intended for this purpose.

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