

## WIDEFJALL Lena

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**From:** AIDUCE <contact@aiduce.fr>  
**Sent:** 04 September 2013 23:16  
**To:** SCHLYTER Carl  
**Subject:** AIDUCE - Don't turn vapers back to tobacco !  
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Dear Member of the European Parliament,

As President of the French independent association of electronic cigarette users (AIDUCE), I am writing to ask you to refuse the de facto ban on electronic cigarettes contained in the draft Directive on tobacco products.

As pointed out by many experts and specialist organizations and as confirmed by the vast majority of the members of user forums, the proposal to classify electronic cigarettes as medicines will effectively eliminate from the market the maj or part of what makes them attractive to smokers.

As a result, hundreds of thousands of European vapers would return to tobacco and tens of millions of smokers would be discouraged from discovering in the electronic cigarette an alternative that, according to the French Office against Tobacco Addiction (OFT), is far less dangerous.

Faced with this threat, in recent months many petitions have been launched across Europe; the one initiated by our Association having collected more than 33,000 signatures from French speakers:  
<http://www.aiduce.fr/petition/>

We are also aware of the illegal nature of this proposal, highlighted by the opinion of the JURI Committee and by many legal experts such as Sir Francis Jacobs QC, the former Advocate General at the Court of Justice of the EU.

Should this proposal be approved by the full Parliament and by the EU Council, the ensuing legislation would be therefore both liberticidal and contrary to the interest of public health. AIDUCE has the means to challenge it in national and European Courts.

To help fully inform you about electronic cigarettes and about the nature of the debate surrounding them, please find enclosed a report based on our own research and on the experience and testimony of tens of thousands of vapers.

We will be attending the European Parliament in Strasbourg on the 9th September where we would be delighted to supply any further information you may require.

Yours sincerely

Brice LEPOUTRE  
AIDUCE President

**Association Indépendante Des Utilisateurs de Cigarette Electronique**  
<http://www.aiduce.fr>



# The future of Vaping in the European Union

Updated 1<sup>st</sup> September 2013



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## Who are we?

We are AIDUCE, the French independent association of electronic cigarette users. 'Independent' means that we are supported only by our members who contribute an annual fixed fee of €10. Commercial entities are refused membership.

We draw our information from our research, from the experience of our members, from those who correspond with us and especially from two large user forums in France. The largest has more than 41,000 registered members. Forum membership is increasing very rapidly, in line with the exponential growth of electronic cigarette users. To protest against the restrictive measures proposed by the European Commission, a French language Web-based petition was recently launched, which so far has received the support of more than 32,000 signatories (<http://www.aiduce.fr/petition/>).

## How safe are electronic cigarettes?

In May 2013, at the request of the French Health Ministry, the Office Against Tobacco Addiction (OFT) published a detailed report which reviewed the research conducted to date and concluded that "the e-cigarette, if correctly made and properly used, is a product that is infinitely less harmful than cigarettes." It established that compared to tobacco smoke, the vapour produced by the electronic cigarette is characterized by "the absence of carcinogen", "the absence of carbon monoxide" and "the absence of solid particles at any significant level".

## Passive vaping

The OFT report found that the health risk due to passive vaping is virtually nil. To quote the report, it is "at the limit of clinical significance"; and "levels deemed to be toxic cannot be reached even when e-cigarettes are used in a room in the most extreme conditions".

The report states that the half-life of vapour droplets is 100 times less than that of tobacco smoke and that there is no exposure to solid particles.

## Inhalation

It is sometimes said that the effects of inhaling propylene glycol (PG) and vegetable glycerine (VG) (the two major constituents of e-liquid) are unknown. This is not true. Concerning PG, the US Environmental Protection Agency, in their Registration Eligibility Decision, concluded "that there are no endpoints of concern for oral, dermal, or inhalation exposure", and that "a review of the available data has shown propylene glycol and dipropylene glycol to be negative for carcinogenicity in studies conducted up to the testing limit doses established by the Agency; therefore, no further carcinogenic analysis is required" and again that "Propylene glycol and dipropylene glycol were tested for mutagenic or genotoxic potential and found to be negative in a battery of studies". It is worth noting that PG is present in certain asthma inhalers.

Concerning VG, the evaluation prepared for the OECD by the UK Environment Agency shows that "the weight of evidence indicates that glycerol is of low toxicity when ingested, inhaled or in contact with the skin" and "Glycerol is free from structural alerts which raise concern for mutagenicity. Glycerol does not induce gene mutations in bacterial strains, chromosomal effects in mammalian cells or primary DNA

damage in vitro." The evaluation concludes that "no further work is indicated, because of the low hazard potential of this substance".

## Article featured in "60 Millions de consommateurs"

Particular mention should be made of a health warning featured in "60 Millions de consommateurs", a consumer magazine published under the aegis of the French Finance Ministry. Claiming to use an innovative research method, the report concluded "henceforth, account will have to be taken of the intrinsic risks associated with the inhalation of e-cigarette vapour, as well as the uncertainty about the impact of this exposure in the long-term". The article generated considerable press comment across Europe, such as the Daily Mail's headline "E-cigarettes are as harmful as cigarettes and could cause cancer, claims study".

The report was greeted with incredulity by many experts including Dr Dominique Dupagne, Dr Gérard Mathern, Dr Jacques Le Houezec, Dr Luc Dussart, Prof Robert Molimard and Prof Jean-François Etter. They question the research methods used, the test protocols, the scientific references, the declarations of interest, the exact quantities of substances claimed to have been detected in e-vapour.

In particular, Dr Konstantinos Farsalinos argues that the article is "nothing new but huge negative publicity and intimidation". He continues "the results are shocking, not because of the concern about the health of consumers but because it once again shows how a study\* can be misrepresented and how much fear and intimidation it has produced to the public (in particular to e-cigarette users) for almost no reason."

\*The study referred to is one on which part of the magazine report appears to be based.

It is possible that the research method used caused the e-cigarettes to overheat to a very high degree; such occurrence being so rare in normal usage that not one of the 2 million posts to France's largest user forum reports such a misadventure.

## Nicotine

Nicotine is a toxic substance. Whilst the precise single lethal dose for a human being is unknown, it is estimated to be from 30 to 60 mg for an adult and about 10mg for a child.

Nicotine has a half-life of about two hours and is completely expelled from the body in 8 to 10 hours.

In normal use nothing indicates that nicotine per se has harmful side effects. Indeed, the US Food and Drug Administration states that "although any nicotine-containing product is potentially addictive, decades of research and use have shown that NRT [Nicotine Replacement Therapy] products sold OTC [Over The Counter] do not appear to have significant potential for abuse or dependence".

The addictive power of nicotine is often mentioned but evidence for it seems to be more anecdotal than quantified. It has been questioned in depth by, in particular, Professor Robert Molimard (see "Le mythe de l'addiction à la nicotine"). It can also be questioned by the fact that nicotine replacement products are singularly ineffective and have rarely been reported to cause nicotine addiction.

## The effect of nicotine on electronic cigarette users

Many people on the user forums discuss the effect on their health of electronic cigarettes compared with their experience as smokers.

On the whole, their evidence is strongly positive; they breathe more freely, they usually exercise more, they note an increase in sexual activity. They also comment on the cosmetic aspects of having sweeter breath, cleaner teeth and clearer skin. Concerning the role played by nicotine, it appears that most vapers seek to reduce the level of concentration and that most succeed in doing so. The level at which they eventually feel comfortable is highly variable according to the individual. A small number report having reduced the level of nicotine to zero. On the other hand, some beginners recount having problems with effecting the transition to electronic cigarettes because they feel an insufficient ‘hit’; the benefit relative to tobacco is not enough and they leave the forums to resume smoking. Some return and succeed in overcoming their difficulties, thanks to the continuous improvement in the offer and the quality of the liquids and equipment..

There are a lot of comments from beginners about the transitory effects of leaving tobacco and adopting electronic cigarettes. They vary enormously according to the individual. Some people have bouts of coughing which disappear over time. The need to drink a lot of water is often stated. Headaches are sometimes reported. They can be due to quitting tobacco or they can be linked to the nicotine concentration of the liquid. Quite quickly, the people concerned learn to adapt their nicotine intake; sometimes to a constant level, sometimes by varying it during the course of each day. They self-dose so that the headaches disappear. No long term deleterious

effect on anyone's health caused by nicotine in e-liquid has been reported.

## Nicotine concentrations available in the EU

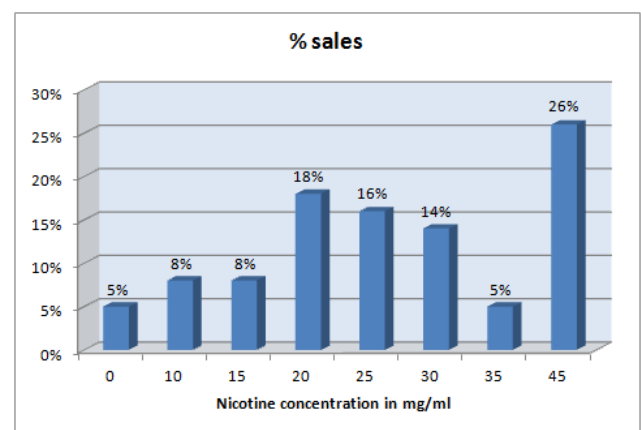
Nicotine patches may contain up to 25 mg of nicotine delivered over 16 hours.

A nicotine gum may contain up to 4 mg; up to 15 can be used every 24 hours and it may be used in conjunction with patches. This gives a maximum exposure to nicotine over 24 hours of 60 to 80 mg.

The NICORETTE® Inhaler contains 10 mg cartridges and the maximum number of cartridges recommended by the manufacturer for use in one day is 12, giving a maximum daily availability of nicotine of 120 mg.

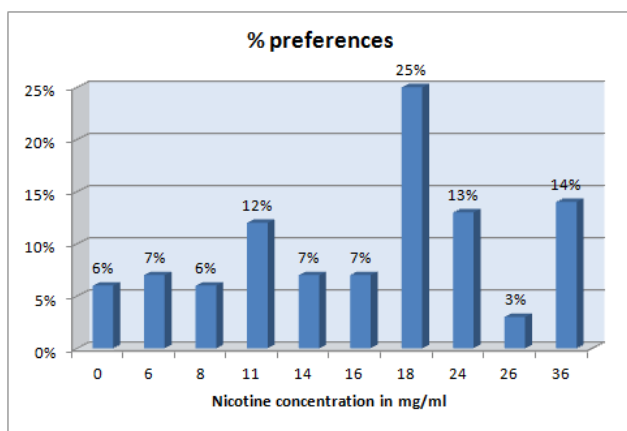
Pfizer's equivalent product, the NICOTROL® Inhaler, contains 10 mg cartridges and the maximum number that should not be exceeded is 16, giving a maximum daily availability of 160 mg.

One British liquid retailer reports the following sales split according to level of nicotine concentration:



The number of users consuming a concentrate of 4.5% (45 mg/ml) is apparently due to a new product which the retailer says is consumed by users who "take less inhalations per day and have found the experience similar to that of traditional smoking".

Another retailer reports the following, drawn from a poll of 13039 users:



According to research conducted by Professor Farsalinos on a Greek sample, 20% of those new to vaping started at a nicotine level higher than 20 mg/ml and only 5% used liquids with 10mg/ml or less.

According to the account of vapers on the UK users' forum, it appears that a significant number of tobacco smokers needed relatively high nicotine concentrations to effect their transition to vaping. Thereafter, most of them move to a lower level, with a small minority eventually choosing liquids containing no nicotine. No long term deleterious effect on anyone's health caused by the consumption of high levels of nicotine has been reported.

In France, where the regulator recommends that only levels below 20 mg/ml may be sold without prescription, it is to be feared that that ceiling impedes a very significant proportion of smokers

from making the transition to electronic cigarettes.

### Reliability of nicotine content

According to the OFT's report, "recent e-cigarettes present nicotine concentrations that are usually (but not always) close to the stated figures and most of them use pharmaceutical grade nicotine."

The report emphasises that since 2010, the manufacture of e-liquids has significantly improved, as confirmed by Professor JF Etter's study of e-liquids published in May 2013, which concluded that "the nicotine content of electronic cigarette refill bottles is close to what is stated on the label".

Nonetheless, doubts persist about a few products. The independent consumer association "UFC-Que Choisir" recently identified certain e-liquids that had concentrations of nicotine at variance with those indicated; including one illegally sold in some French pharmacies.

Such variances contravene the regulations on general consumer products; rules that should be enforced by the relevant authorities.

### The importance of flavourings

Up till recently, most beginners declared having started vaping with tobacco flavours. There is evidence however that with the arrival on the high street of a rapidly increasing number of specialised shops offering new customers the opportunity to try them out, more beginners are now starting with other flavours. In any case, most vapers who started with tobacco tastes quickly move on to others that are completely different. They are now hundreds including apple, vanilla, cherry, various kinds of chocolate



or coffee. They are especially enjoyed by vapers who have completely quit smoking and who comment on how much their taste buds have recovered their sensitivity. Sampling different flavours excites much passionate debate, with the proponents of one exchanging their appraisals with those of another. Together with the choice of nicotine level, or of the kind of equipment used, what most stands out is the extent to which individual preference varies.

## Product quality

Until a few years ago, users complained about malfunctioning batteries or leaking cartridges. Such complaints are now rare and nearly always concern products that do not bear the name of a recognised manufacturer.

Products are always accompanied by health and safety warnings and vapers are aware of the need to observe them.

It is clear that the recognised manufacturers are abiding by the safety requirements demanded by the General Product Safety Directive and by the related Directives and regulations. These rules probably explain why so few incidents of defective products are now reported.

Concerning electrical safety, it is surprising how few accidents have been reported given that tens of millions of electronic cigarettes have been and are being used. One that is often cited is that of the explosion of a battery in Florida early in 2012 causing serious injury to its owner. The numerous reports of the incident fail however to stress that the battery concerned had probably been modified by the user. It should be noted that restricting access to the range of products currently available is likely to encourage more personal modification, thereby creating the conditions for more accidents to occur.

Concerning what is known as e-liquid, very few accidents have been reported which again is

surprising given the vast number of bottles in circulation. We are aware of only two. One is quoted by the German Cancer Research Centre (DKFZ) to support their view that e-cigarettes should be severely controlled. The link DKFZ provides shows that it involved a patient who suffered asthma, reported rheumatoid arthritis, fibromyalgia, schizoaffective disorder, and hypertension. Her medications included amlodipine, albuterol metered dose inhaler, lovastatin, lisinopril, multiple vitamins, cyclobenzaprine, citalopram, and multiple psychiatric medications. She developed lipid pneumonia after starting to use an electronic cigarette and upon ceasing the practice, her symptoms improved. This case can hardly be considered typical and the fact that it is stressed by the DKFZ indicates that the organisation must have been short of anti e-cigarette arguments.

The second case is that of a little girl who died after drinking a bottle of liquid nicotine. This tragedy, which occurred outside the ambit of EU regulation, emphasises that whatever the concentration of nicotine, the same precautions should be taken for phials as would apply to any hazardous household product: they should be kept secure and away from the reach of children. It should be noted that bottles containing very high concentrations of nicotine are used when mixing liquid at home rather than buying it ready-made (a practice called Do It Yourself or DIY). Banning liquids that contain flavouring would encourage more people to DIY, resulting in the probability of more accidents.

## Are electronic cigarettes gateway products?

Several studies show that electronic cigarettes are not, for non-smokers including the young, gateway products towards tobacco addiction.

In 2012, research by the US Cancer Institute, the Yale School of Medicine and the Medical

University of South Carolina concluded that "ENDS [Electronic Nicotine Delivery Systems] use is almost exclusively concentrated in current smokers and non-smoking youth who are more susceptible to become cigarette smokers in the future. Youth not otherwise susceptible to smoking appear to have little interest in ENDS."

In May 2013, the British anti-tobacco association ASH published a survey of 2173 young people about their usage of electronic cigarettes. It shows that "among young people who have never smoked 1% have tried e-cigarettes once or twice, 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon".

In the same month, the UK Society for Research on Nicotine and Tobacco published a study that concluded "The use of e-cigarette is largely confined to smokers and ex-smokers... While we found evidence supporting the view that e-cigarette use may be a bridge to quitting, we found negligible evidence of e-cigarette use among those who had never smoked. The failure to support and educate smokers on the effective use, risks, and benefits of e-cigarettes may represent a lost opportunity for public health".

In France, a study on children and tobacco, called "Paris Sans Tabac", was published in February 2013. It included a question about electronic cigarettes. It provoked a flurry of press comment which was almost entirely based on deformed or invented data.

For example, Le Monde and Libération were amongst many in the media who said that 64.4% of e-cigarette experimentation among 12 to 14 year olds was by non-smokers.

Where did this figure come from? The study was published under the title of "E-Cigarette: A New Tobacco Product for Schoolchildren in Paris". The title, perhaps worded to attract press coverage, is completely contradicted by the statistics in the body of the report.

In examining the study, we discover that out of the 3409 children who were questioned, 277, or 8.1%, said that they had tried an electronic cigarette. Curiously, the study does not clearly state what proportion of the total population were smokers; other sources indicate that it is about 23%.

So how many children have tried electronic cigarettes without ever having been smokers? The number is 47; that is, 1.4% of the total sample. These 47 children were not however asked whether, having tried electronic cigarettes, they continued to use them.

The study does tell us the proportion of 12 to 14 year olds who have experimented electronic cigarettes: it is 6.4%. Clearly, virtually all of them were already smokers.

The recently published OFT report, drawing from the same study, indicates that only 1.6% of young people who have used or are using tobacco state having first experimented with an electronic cigarette.

It would seem that a campaign of disinformation had been launched and still today, specious figures are circulating to justify the claim that electronic cigarettes are being used by the young as a gateway to tobacco.

## **Why is there such a furore about electronic cigarettes?**

The facts, as we have outlined above, show that for most products current EU regulation now ensures consistent adherence to product safety and labelling standards. Although tens of millions of products are in circulation, there have been virtually no accidents. Correctly used, no deleterious effect on the health of users has been reported, including when consuming what might be considered to be high concentrations of nicotine. Only around 5% of users are on zero

nicotine. For most users, flavourings are critical to maintaining the attractiveness of electronic cigarettes as an alternative to smoking. We have shown that restrictions on the availability of electronic cigarette equipment and on flavoured liquids will lead to more Do It Yourself. We have established that there is no hard data that might imply that electronic cigarettes are a gateway product; indeed the facts demonstrate the opposite.

So why is there such pressure for further regulation which would restrict access for smokers to a product infinitely safer than tobacco?

We detect the influence of three interest groups.

## 1. The tobacco industry

Sales of smoked tobacco are falling. Those of electronic cigarettes are increasing very rapidly. The industry is reacting on two fronts.

Some companies are developing products that will be on general sale, targeting first the US market where electronic cigarettes are likely to be classified as tobacco products. The first product to be commercialised is a 'lookalike', that is, it looks almost identical to a tobacco cigarette. The only flavours available are tobacco and menthol. It has been tested by experienced vapers who consider it to be interesting as a gadget, but one that offers a poor vaping experience. Given that vapers who have discovered electronic cigarettes through 'lookalikes' tend to move on to more sophisticated equipment and flavours, it is unlikely that such products risk dominating the market.

Another approach is being taken by BAT (British American Tobacco) who bought a British manufacturer that was going through the process of seeking medicinal approval for its

product. Their electronic cigarette is also a 'lookalike' and again, only tobacco and menthol flavours are offered. According to one report, the approval process has taken three years and cost €2 million. The commercial strategy behind such an investment must be to position BAT to capitalise on the possibility that electronic cigarettes will be classified as medicines, which would eliminate competition from the more popular liquid makers. This intention seems to be confirmed by the enthusiasm with which BAT greeted the announcement that the British regulator seeks to require electronic cigarette makers to obtain medical certification.

## 2. The pharmaceutical industry

Sales of electronic cigarettes are expected this year to overtake those for the pharmaceutical industry's authorised nicotine replacement products. This isn't surprising. France's CNRS in 2009 and the Harvard School of Public Health in 2012 demonstrated that the efficacy of authorised nicotine replacement products is extremely poor, averaging at less than 7%. That of Pfizer's psychotropic drug varenicline (marketed as Champix) is higher, but it is associated with mood changes, depression and over 200 suicides.

None of these products elicits the affection of their users. Yet the electronic cigarette does. Tens of thousands of vapers express their enthusiasm on fast growing forums. But instead of greeting the electronic cigarette as an infinitely safer alternative to smoking, instead of recognising it as a unique opportunity to save millions of lives, the pharmaceutical industry complains, as expressed by the European Commission in its staff working document, that "if other NCP [Nicotine Containing Products] can reach the market without... authorisation, it could lead to an unjustified advantage undermining a level playing field". The concern is not about public safety, but about competition.

According to the HAI/CEO report on the pharmaceutical lobby, the industry declares spending more than €40 million annually to influence decision making in the European Union and the report reckons that actual expenditure may be as high as €91 million annually. Civil society organisations active on EU medicines issues spend altogether a mere €3.4 million per year. To quote the report: "with the immense disparity between the affluence of public interest groups and the industrial lobby, it becomes even more difficult to level the policy playing field".

The pharmaceutical industry's influence is often indirect but it is pervasive. For example, Pfizer, with other pharmaceuticals and together with the European Respiratory Society (which opposes electronic cigarettes), founded the European Chronic Obstructive Pulmonary Diseases Coalition (COPD). The coalition reaches out to MEPs and one of them, who sits on the ENVI commission, stated in her blog in 2011 "I have been getting involved with the newly formed European COPD Coalition as we look towards revising the Tobacco Products Directive next year". As the HAI/CEO report comments, stricter legislation on tobacco products is a reasonable objective, but it would have been more transparent for her to make it publicly clear that she was consulting with an organisation representing several pharmaceutical companies, including Pfizer which produces a medicine to aid smoking cessation.

A great many experts and scientists in this field of research have links, some of them close, with the pharmaceutical industry. For example, of the ten experts who compiled the OFT report on electronic cigarettes, five report such links, including one as a paid consultant. However, only one of the experts declared a link with the electronic cigarette industry, which amounted to the reimbursement of an air fare to China. The OFT itself declares having had numerous

contacts with the pharmaceutical industry. This proximity is not surprising, given the preponderant weight of the industry in scientific research. It does however create an imbalance of influence when examining a product with which it competes. It may help to explain why most of the OFT's recommendations are inconsistent with the data and with the hard evidence set out in the body of its own report.

In particular, one of the recommendations seems, perhaps unwittingly, to have been particularly oriented by this influence. It proposes that "studies, which must be completely independent of their manufacturers, should be encouraged on the effectiveness of e-cigarettes in smoking cessation and on the safety of their long-term use". Why should the studies be independent only of e-cigarette manufacturers? Why was the pharmaceutical, and for that matter the tobacco industry not mentioned? As we noted in our analysis of the report, would it not have been more judicious to insist that all funding, regardless of origin, be disclosed and transparent?

As Professor JF Etter concludes, "If speaking openly about a collaboration between the political powers and the pharmaceutical industry seems farfetched right now, no one can deny that the 'death' of the e-cigarette would be good news for pharmaceutical groups".

### 3. The proponents of 'denormalisation'

The World Health Organisation's argument against electronic cigarettes is based on the claim that they 'normalise' smoking. To quote Professor Michael Siegel's response "what the World Health Organization is saying is that electronic cigarette use is unacceptable because it 'looks like' smoking. The WHO is willing to let this ideological obsession outweigh the tremendous potential for public health benefits and the saving of lives that electronic cigarettes

offer. In other words, the World Health Organization is telling countries that it is more important to discourage any behaviour that looks like smoking than it is to save the lives of smokers".

The French League against Cancer is typical of organisations who have become confused about their objectives. Rather than seeking to improve the health of smokers by encouraging them to choose less harmful alternatives, they want to control their gestures. "The electronic cigarette maintains the smoker's behavioural dependence" they say, and "harms denormalisation the objective of which is to stamp out the presence of tobacco addiction in everyday life". To support its argument, the League then claims that schoolchildren often use electronic cigarettes before moving on to tobacco, which, as we have demonstrated, is false.

The belief that the real fight is against behaviour, against a gesture, has even led to a Minister of Health to seek to forbid vaping from wherever smoking is banned because, she says, "vaping is smoking". She appears to subscribe to the dogma that people's behaviour has to adhere to a socially prescribed norm.

## **Medicalising electronic cigarettes will kill vaping as we know it today**

According to the testimony of thousands of vapers on their forums, they did not choose the electronic cigarette because of a specific promise that it would improve their health; for no such promise is made. They turn to it with the hope that it will be as pleasurable as smoking thus facilitating a reduction or a cessation of their tobacco consumption. In what seems to be the vast majority of cases a significant reduction or a cessation does indeed occur. What is startling is that the ways in which they are achieved are extremely variable from one person to another.

For example, some people prefer very high levels of nicotine, enabling them to draw far fewer puffs than those who use lower levels. Over time, they may however choose a different pattern of consumption. Other people set an objective to reduce the nicotine content, playing with different flavours to help them achieve it. Some people like to retain the throat constriction which is known as the 'hit' with quite high levels of nicotine, whilst also trying out different flavours. Some adopt a particular flavour for a period of time and then move on to another. The frequency of use also varies; the same person might puff a lot one day and hardly at all the next. There are people whose prime objective is to reduce cost; they trawl the Net to find the cheapest suppliers or turn to DIY.

Just as wide a variety exists for the equipment. Some people will choose complex batteries that allow the voltage to be varied, combined with atomisers that have different levels of resistance. They talk about the difference between hot and cold vapour. Others prefer simpler devices. There is much debate contrasting the merits of cartomisers and clearomisers. Many people combine different types, depending on whether they are at home, at work, or travelling. Several more pages would be needed to detail all the available options, which all have their enthusiastic supporters.

It has to be said that there are also people who simply do not take to electronic cigarettes. Some are put off by their relative complexity; after all, tobacco cigarettes are easier to use and are far more readily obtainable. Some just do not like the experience. It is also noticeable that in France, where higher rates of nicotine are not available, a significant number of smokers are deterred from vaping because they need a higher level to effect the transition.

How could such a range of products, such a rich variety of choice, be medicalised?

As Professor Konstantinos Farsalinos said in June 2013: "medicinal regulation means that you should define specific dosage, determine consistent nicotine delivery and give specific instructions of use. These are impossible to implement in e-cigarettes since every consumer has a different pattern of use... NRTs have failed for the same reasons (among others). Now, imagine prescribing e-cigarettes with a dosage like "15 puffs lasting 4 seconds, every 4 hours"... E-cigarettes are effective because they provide pleasure to the user. And every consumer has a different perception of pleasure. This precludes any efforts to regulate it as medication."

Choice and variety explain the success of electronic cigarettes. Reducing choice and variety will reduce their attractiveness.

According to Emeritus Professor Gerry Stimson, one of the founders of Harm Reduction, "Rather than over-regulation, we should be moving towards encouraging the use of electronic cigarettes and other NCP, rather than putting obstacles in the way of smokers. It is bad Public Health policy to make it harder to obtain safer products than tobacco cigarettes."

Clive Bates, a tobacco control advocate and former Director of Action on Smoking and Health UK, agrees: "Medicines regulation should apply to medicines, and electronic cigarettes are not medicines. These products are consumer alternatives to cigarettes - they provide nicotine in a much less harmful way than cigarettes and manufacturers do not make health claims, so why should they face high regulatory burdens?"

Professor JF Etter commented in a recent interview: "It would be a mistake I think to regulate these products as medications, and if they were regulated as medications this would limit access to the product too much and cause many deaths. There is a debate between policy-makers who are very conservative and very risk averse, and are ready to regulate these as

medications, and the public who appreciates the product and uses it. Astonishingly, the most vocal opponents of e-cigarettes are people from the public health community, who perhaps don't understand what is at stake, and just don't like the product because it looks too much like a cigarette. If regulators could let the market evolve without regulating it too much and without regulating it unjustly... because currently people who are addicted to cigarettes are condemned to use tobacco, these laws arguably kill millions of people. They are absurd because they block every competitor to cigarette makers. So there's a need to let competitors to enter the nicotine market so more people will switch from smoking to e-cigarettes and this will save many lives."

We therefore support the OFT's recommendation that "France should request the exclusion of Article 18 from the draft EU directive on tobacco products".

## The Law

We are aware of the opinion of the European Parliament's Committee on Legal Affairs (JURI) on the Commission's proposed Tobacco Products Directive:

"The requirement of authorisation of nicotine containing products pursuant to Directive 2001/83/EC could seriously restrict access to products which are less harmful than tobacco products and which can help tobacco consumers to quit. Additionally, the measures proposed cannot be based on Article 114(1) TFEU and therefore lack any legal base."

We are aware of the following seven decisions and formal opinions which rejected attempts to bring electronic cigarettes and food products within the ambit of a medical classification: Estonia, Tartu Administrative Court, Case No. 3-12-2345, March 2013; The Netherlands, s-

Gravenhage Court, Case No. 414117, March 2012; Germany, Administrative Court of Köln, Case No. 7 K 3169/11, March 2012; Germany, Supreme Court of Sachsen-Anhalt, Case No. 3 M 129/12, June 2012; European Court of Justice, Case No. C-140/07, January 2009, preliminary ruling in the case of Hecht-Pharma GmbH -vs- Staatliches Gewerbeaufsichtsamt Lüneburg; Commission of the European Communities -v- Federal Republic of Germany, Case No. C-319/05, November 2007; Counsel Opinion of Advocate-General Geelhoed on joined cases C-21103, C-299/03 and C-316/03 to C-318/03, February 2005.

We are aware of the opinion of Sir Francis Jacobs QC, President of the European Law Institute and former Advocate-General to the European Court of Justice, who considers a de facto ban on electronic cigarettes to be a very extreme and intrusive form of regulation. It would constitute “an unreasonable measure which is liable to be annulled as being contrary to the principle of proportionality and/or the principle of non-discrimination”.

We are aware that the Medicinal Products Directive 2001/83/EC cannot apply to a product that has not been scientifically established as a medicinal product by function.

We are aware that the free movement of goods within the European Union is one of the freedoms of the single market and we wish to retain it.

We are prepared, together with other Users' Associations in Europe, to contest in the Courts any challenge to these basic principles.

## Vapers are not pariahs

Before becoming vapers, the only thing we had in common with each other was that we smoked. As smokers, the authorities, as a means to combat tobacco addiction, encouraged the rest of

society to treat us as pariahs. Today we have discovered a practice that we enjoy, that according to all the latest evidence is infinitely less harmful than tobacco and which does no harm to anyone else. For many of us it has become a hobby; including for people who prefer to use nicotine-free liquids. It is a practice attracting a fast growing number of smokers who hope to join a community no longer ostracised by everyone else.

Yet, because of this very success, once again we are subject to disdain and social banishment. A government minister tries to decree that we should still be treated as smokers. Legislation is proposed that would reduce the attractiveness of vaping for smokers. The fact that the rich variety of flavours is a key part of vaping is brushed aside. Ceilings of nicotine concentration are proposed on the basis of no quantified scientific evidence whatsoever. Claims based on specious evidence continue to circulate that the electronic cigarette is a gateway product.

We want to be treated as ordinary people. We refuse to be told that electronic cigarettes are distorting some competitive level playing field, the rules of which are set by big industrial interests who offer products few people want. We are responsible adults, not children to be instructed on how to behave by some paternalist authority.

Specifically, we want electronic cigarettes to be explicitly recognised as general consumer goods. We are pleased with the way the ensuing directives and regulations are increasingly ensuring reliable adherence to proper safety and labelling standards. We believe that the rules on advertising should be set at national level. Restrictions on vaping in public places should be the responsibility of their owners and not of the state.

Please support our right to individuality.

We leave you with the words of John Stuart Mill:

“Neither one person, nor any number of persons, is warranted in saying to another human creature of ripe years, that he shall not do with his life for his own benefit what he chooses to do with it. He is the person most interested in his own well-being.... The interference of society to overrule his judgment and purposes in what only regards himself, must be grounded on general presumptions; which may be altogether wrong.”  
(On Liberty, 1859)