

OPINION

concerning the risks and benefits in the use of electronic cigarettes by the general population

25th April 2014

The use of electronic cigarettes (or e-cigarettes), as a novel means of inhaling nicotine-containing substances, is a phenomenon that has taken hold in France, as elsewhere. As with traditional cigarettes and tobacco products in general, the nicotine concentration in an electronic cigarette can vary (in theory between 0 and 20 mg/ml). And this method of obtaining nicotine doses is seeing considerable growth. According to the ETINCEL survey carried out by the Observatoire français des drogues et des toxicomanies (the French body monitoring drug addiction) (OFDT, 2014), 75% of electronic cigarette users started less than six months ago. Today, according to the same survey, roughly one in five French people had tried an e-cigarette at least once by the end of 2013, some 2.5 times the number in March 2012. Usage within the month concerns one person in 15. And finally, 3% of the population are daily users, representing some 1.5 million citizens (OFDT, 2014).

The use of this modern, non-pharmaceutical, industrial product is perceived as an 'alternative' to tobacco and the practice of smoking. The potential reduction of the risks linked to tobacco¹ smoke is of crucial importance given the level of tobacco-related illnesses and mortality, especially as the electronic cigarette is presented as a means of helping people to overcome their dependence on tobacco, and many users see it as a real ray of hope of completely breaking the habit. The electronic cigarette is seen, first, as a means of reducing the number of cigarettes smoked and then as the route to an end to tobacco smoking altogether.

The European Commission is starting to legislate on e-cigarettes. Certain countries already have measures in place to regulate sales and consumption. In France, a first report on the subject was published in 2013 (OFT, 2013) in which the experts consulted highlighted the areas of uncertainty. They made twenty-one recommendations, in particular: "*that access to e-cigarettes by smokers should not be limited*"; "*to put in place measures to prevent advertising and access to e-cigarettes by minors and people who have never smoked*"; "*to regulate on e-cigarettes*".

The High Council for Public Health (HCSP) has carried out, on behalf of the Inter-ministerial mission on fighting drugs and addictive practices (MLDECA - pour Mission interministérielle de lutte contre les drogues et les conduites addictives), an analysis of the literature concerning the risk-benefit ratio on e-cigarette usage and of its potential consequences for the population in general.

The risk-benefit ratio needs to be handled with care given:

- the few scientific studies carried out to date (Caponnetto, Campagna et al. 2013; Bullen, Howe et al. 2013; Bullen, Williman et al. 2013; HAS, 2013) do not demonstrate any significantly greater effectiveness in stopping the consumption of tobacco compared with the traditional nicotine substitutes such as patches;

1. Tobacco smoke contains many toxic substances, among which can be cited CO, benzene, formaldehyde, tars, nicotine, cadmium, polonium, etc.

- the ETINCEL inquiry (ODT, 2014) reveals that very few smokers have changed to 'exclusive' use of personal vaporisers: about 1% of e-cigarette uses are in this category (but the use of electronic cigarettes is sufficiently recent among the majority of smokers that there is a lack of suitable experience). These results need to be verified by further studies.

Whereas any positive effects from the use of e-cigarettes can only be considered as relatively limited, given the current state of the art, one should not be surprised by negative effects:

- first of all, there is a high risk of the inhaling or smoking of nicotine, in whatever form, becoming 'normalised', especially if and when powerful commercial interests take hold of the product;
- young people, attracted by the novelty and particularly tempted by the use of psychotropic substances, could be particularly concerned; electronic cigarettes could be the conduit to standard tobacco dependency.

In the light of this, the HCSP has taken the following into consideration:

- 1. The very high risks linked to tobacco consumption**, the consequences of which in terms of disease (cancers, cardiovascular afflictions) and fatalities (73,000 deaths per annum in France) are considerable Hill, 2012).
- 2. The decrease of 6.2% in sales of tobacco by tobaccoists in 2013** (OFDT, 2014). The reasons for such a large drop are probably many and varied: increase in the sales price, less discretionary income, cross-border shopping, the effect of e-cigarettes. A drop in tobacco sales means less tobacco consumption: on average, lower quantities smoked per smoker, but not necessarily by having fewer regular smokers (this latter figure will be checked using a much larger sample using 2014 data at the end of the year, but the preliminary surveys would suggest a certain stability in this indicator) (Guignard et al. 2013).
- 3. The very limited effectiveness** shown by e-cigarettes (with or without nicotine) **in reducing tobacco dependency**. As for abstinence - which is the most relevant public health indicator, since a simple reduction has very little effect on health (Tverdal and Bjartveit, 2006) - the effectiveness of e-cigarettes (with or without nicotine) is similar to that of nicotine patches. It is around 5-7%² for the population having a moderate level of addiction (FTND³ average of 5) (Caponnetto, Campagna et al. 2013; Bullen, Howe et al. 2013; Bullen, Williman et al. 2013 ; HAS, 2013). As for reducing cigarette consumption, e-cigarettes (with or without nicotine) are more effective than patches: the difference is two cigarettes per day. A point worth noting is that the presence or absence of nicotine in the e-cigarette would appear to make little difference⁴.
- 4. The arguments used to promote electronic cigarettes as a tool in reducing the risks of tobacco addiction**. The use of e-cigarettes by smokers, without any tobacco consumption, is a means of reducing the risks for that population. However, concurrent consumption of tobacco and e-cigarettes (such people are called "vapofumeurs") means that one is unable to say that tobacco-related risks diminish to any significant degree (NICE, 2013). In reality, tobacco-related risks are a function both of the quantity of cigarettes smoked, but also of the duration of the exposure to the risk - the 'time' factor having a greater influence on lung cancer development than the 'dosage' factor (Doll and Peto, 1978)⁵ ⁶. Thus reducing consumption is a less effective strategy than reducing the time over which smoking has been taking place i.e. stopping tobacco smoking. Electronic cigarette smokers who continue to smoke tobacco will see a lesser reduction in tobacco-related risks. The ETINCEL survey, however, shows that only a tiny proportion of regular "vapers" have completely dispensed with tobacco. All this needs to be confirmed and refined in order to monitor over

² Over periods of 3, 6 or 12 months.

³ FTND = Fagerstrom Test for Nicotine Dependence (Fagerstrom, 1978)..

⁴ A problem of statistical power in the study does not, however, enable definitive conclusions to be drawn on this subject.

⁵ Doubling the dose of tobacco doubles the risk of lung cancer, doubling the exposure time multiplies this increased risk by 20 [16 and 32] (Hill, 1999).

⁶ Doll and Peto carried out a survey among smoking British doctors, aged between 16 and 25 at the time of their inclusion in the study, and monitored over 20 years and assessed the annual incidence of lung cancer. Their model has enabled calculating the probability of lung cancer using the following equation $0.273 \times 10^{-12} (\text{cigarettes}/\text{day} + 6)^2 * (\text{age} - 22,5)^4$ ⁵.

time the number of cases of people ceasing to smoke tobacco as a result of using electronic cigarettes. In the same way, the preliminary results of a recent American study in 2011-2012 (which need to be confirmed) carried out among smokers does not show, after one year, a greater rate of cessation or reduction of tobacco smoking among the vapofumeurs compared with those who do not use e-cigarettes (Grana et al. 2014).

5. The effects of nicotine on health.

- > **Nicotine is addictive in humans.** The intensity of nicotine dependence is stronger than that induced by alcohol, cannabis or the synthetic drugs, and is close to that of cocaine and heroin (OFT, 2013; Goodman and Gilman's, 2011).
- > **Nicotine produces anxiety and stress** resulting from the many attempts at breaking the habit and the daily craving that it produces, although during consumption it has a calming effect.
- > **Nicotine has a long-term depressive effect** (and depression is one of the principal disorders in industrialised societies (Picciotto and Mineur 2014). Stopping smoking improves mental health, in particular the state of depression, and the effect of such cessation is greater than that achieved by conventional anti-depression treatment (Taylor, McNeill et al. 2014).
- > **Nicotine is an appetite suppressant** which could be a reason for young or vulnerable people to experiment with e-cigarettes.
- > **Nicotine is neurotoxic in children** in particular during the development stages, and early exposure to nicotine is associated with an increased risk of tobacco/nicotine consumption in later life. Uterine exposure to nicotine affects the foetus's attention circuits and is associated with an increase in problems of attention later (Picciotto and Mineur 2014).
- > **Nicotine has also an immuno-depressive effect** and increases the secretion of pulmonary mucus (Zyl-Smit 2013); it is part of the apoptosis process and is potentially implicated in carcinogenic processes also (Zeidler, Albermann et al. 2007).
- > Finally, **a pre-clinical American study has called for an assessment of the potential cancer risk** from e-cigarettes in people prone to such pathologies. This study shows that exposing mutation carrying cells from smokers or former smokers, with lung cancer, to nicotine-containing 'vapour' in vitro has been found to favour the invasive growth of such cancerous cells. Furthermore, in cells exposed to e-cigarette vapour, there is evidence of modified gene expression that is very close to that caused by tobacco smoke (Spark et al., 2014).

With regard to the effects of nicotine on health, the same arguments could well be true for the traditional nicotine substitutes (patches, gums, etc.). It needs to be borne in mind, however, that the latter, unlike electronic cigarettes, have been authorised to be in the marketplace which has enabled an assessment to be carried out of both the therapeutic benefits and the side effects. In addition, they are sold in pharmacies and therefore professional advice is possible - the products are seen as a logical part of breaking the smoking habit (frequently also initiated by the patient's doctor or a smoking cessation advisor who is capable of advising on appropriateness and dosage). Finally, and above all, the bioavailability of nicotine administered through e-cigarettes is greater than that from existing nicotine substitutes. Furthermore, it produces very high blood plasma, and even arterial, concentrations accompanied by a flash effect (levels between 7.4 ng/ml and 11 ng/ml just 5 minutes after the e-cigarette 'consumption' (Vansickel, 2012 and 2013)), and this even with smokers, who possess a certain tolerance level. This can cause coronary constrictions (angor) and hypertension through peripheral vasoconstriction - with the potential risk of a stroke. This flash effect is, moreover, one of the characteristically addictive properties of nicotine, which is specifically avoided by the pharmacokinetic specifications of traditional nicotine substitutes (Fant, 2000).

6. **The low level of toxicity, a priori, in the other substances contained in an e-cigarette.** There would seem to be no major short-term health problems, neither for the active consumer, nor for people who are exposed passively to the 'smoke' (Burstyn, 2013). However, there is very little documented information on the long-term toxicity of propylene glycol, vegetable glycerine and synthetic flavourings, etc. In addition, for a product that is already widely consumed, there is a marked lack of information concerning the production of e-liquids, and a complete absence of labelling and certification standards at both national and European levels (N'Sondé, 2013).

7. **Certain forms of acute intoxication:** by *vaping* (Hureaux, Drouet et al. 2014; McCauley, Markin et al. 2012), by accidental ingestion of nicotine containing products, especially by children (Cervellin, Luci et al. 2013; Cameron, Howell et al. 2014), or in cases of deliberate abuse as in drug addiction and suicide attempts (Thornton, Oller et al. 2014).

8. **The level of experimentation by the very young.** Electronic cigarettes would appear to be a convenient way for the young to start the nicotine experience (Pepper et al. 2013; McBride, 2014).

In Paris, an initial survey, carried out in the first quarter of 2012 (thus well before the widespread availability of e-cigarettes) among some 3,400 adolescent school children aged between 12 and 19, shows that the percentage of 12-14 year-olds experimenting with e-cigarettes is higher than for those experimenting with tobacco (6.4% versus 6%) (Datzenberg et al., 2013).

In the United States, two cross-sectional surveys were carried out in two waves in 2011 (178 schools) and in 2012 (228 schools) among more than 40,000 adolescents aged between 14 and 15, using a self-administered questionnaire and carried out anonymously. These show that the use of e-cigarettes carries with it much greater risks of having been, or of currently being, cigarette smokers, and also a much greater risk of already being nicotine dependent. This link is also perceived in the level of intention to cease tobacco smoking. Among those who experiment with cigarettes, the use of electronic cigarettes is linked to a much lower chance of abstaining from tobacco use⁷. The conclusion of the authors is that the use of e-cigarettes is not an incentive to cease tobacco smoking, and can even encourage American adolescents to smoke conventional cigarettes (Dutra and Glantz, 2013).

Finally, being hooked on tobacco in early adolescence increases the relative mortality risk. A study was carried out in the UK among some 1.3 million women recruited between 1996 and 2001 with an average monitoring period of 12 women-years. This showed that the age at which they started smoking affects the relative mortality risk. Those who started at the age of 15 had a greater risk (RR⁸ = 3.2) than those who started 4 years later (RR = 2.9) or at age 28 (RR = 2.4) compared with non-smokers (RR = 1) (Pirie K, 2012). Any mechanism, such as e-cigarettes, that incents an early nicotine experience - this is typically the case among adolescents - and the subsequent transfer to tobacco, is likely to increase the mortality rate in the long term.

9. **Marketing strategies for electronic cigarettes.** Apart from the fact that an advertising strategy based on the idea of breaking the tobacco habit flies in the face of the evidence of effectiveness, the communications and marketing strategies for electronic cigarettes resemble those of the tobacco giants who are now investing heavily in e-cigarettes. This plays on the usual themes of sensuality, sexuality, variety, humour, technology, science etc. and, with e-cigarettes being in open distribution, the possibility of using the Internet for promotion and sales adds a further outlet to the traditional distribution channels (Paek, Kim et al. 2013; Richardson, Ganz et al. 2014).

Thanks to this increasingly powerful marketing (Kim et al. 2014), the electronic cigarette has gained a socially favourable place in the minds of the general public. One is seeing the emergence of a 'vaping' culture, with its own community of 'vapers', which is helping to create a positive social image. Finally, the e-cigarette is taking the debate way beyond the idea of tobacco cessation, and is being considered as a 'surer' and more controlled means of consuming nicotine, which is increasingly being seen as a pleasant pastime where one can enjoy the various flavours on offer (Barbeau, 2013).

Another example is the April 2014 launch of a new method of tobacco consumption. This is similar to the electronic cigarette but consists of tobacco vaporisation in a new product called "Ploom" which is "of an elegant, almost futuristic, design" (Les échos, 2014).

The risk is that we shall be seeing a re-normalisation of the smoked product, and of the debate surrounding the presentation of nicotine consumption, be that inhaled or smoked. In other words, e-cigarette marketing could be seen as a form of indirect advertising for tobacco, as well as for the social acceptance of the electronic cigarette. The risk is particularly acute given that the tobacco industry is in the process of buying up e-cigarette companies. The marketing strength of this industry is well known (Proctor, 2014).

In this regard, it is worth noting that, in February 2014, faced with the appearance of advertising spots promoting the electronic cigarette on certain radio and television channels, the French audiovisual watchdog addressed the following questions to the Minister of Health:

⁷-amongst regular users of e-cigarettes, the probability that conventional smokers will cease to smoke tobacco (at 1 month, 6 months and one year) is three times less than for those who do not use e-cigarettes-

⁸-RR = relative risk.

- o "Should electronic cigarette advertising be considered as advertising or propaganda, either direct or indirect, for tobacco, tobacco-related products or ingredients as defined in article L. 3511-1 of the Public Health Code?
- o Could the electronic cigarette be considered as a medicinal product within the meaning of article L. 5121-2 of the Public Health Code?
- o To which legal category, within the meaning of the Public Health Code, does nicotine belong? "

10. The purchase of e-cigarette companies by the tobacco industry (Revue des tabacs, 2012 ; Le Monde, 2014). Can one deduce from the entry of the tobacco industry into the e-cigarette market that electronic cigarettes are not a complete substitute for tobacco, and that consumption of one can promote the consumption of the other, since both products have the common objective of delivering the highly addictive product, nicotine? Or is it just possible that the tobacco industry needs to be in this new market in case e-cigarettes one day replace tobacco?⁹ Whatever the reason, electronic cigarettes will be promoted massively by an industry whose marketing clout and influence are no secret for anyone.

11. The purchase price of e-cigarettes and the e-liquid refills. There is a doubt about the savings that a smoker would make if he chose e-cigarettes to replace his daily consumption of one packet of cigarettes a day. In fact, there are question marks about battery quality - how frequently should they be changed? - and about the refill consumption rate: are the number of inhalations and the nicotine dose monetarily equivalent to the tobacco products replaced? The question is still open (N'Sondé, 2013). In the short term, it is likely that e-cigarettes will be the subject of significant differentiation by their design and the flavourings on offer. And then it is necessary to take account of possible taxation of such products in the future. A system of monitoring the sales prices for e-cigarettes should be considered.

12. The new European Directive concerning tobacco products (to replace the "Tobacco Products Directive" (2001/37/EC)) will establish the requirements to be met by e-cigarettes in the areas of safety and quality. Among other items, producers will be required to provide more precise information for consumers - health messages on e-cigarette packaging, a user guide, information concerning nicotine addiction and toxicity, a list of substances present in e-liquids, etc. In addition, producers will be obliged to inform member States of any new product launch, with expected sales volumes, type of customer targeted, market trends and preferences, etc. Once announced in the European Union's Official Journal, member States will have two years to incorporate this into their respective national legislation. These new regulations will not apply to electronic cigarettes for medical use (in line with Directive 2001/83/CE), nor to any medical devices (Directive 93/42/CEE), but will apply to all electronic cigarettes for general consumption throughout the European Union.

13. The current regulations in the United States and the countries of Western Europe (DAEI, September 2013).

In the United States there is no federal legislation. Certain States prohibit sales to minors (California, Colorado, Minnesota, New Hampshire, New Jersey, Tennessee). Several counties have banned the use of e-cigarettes in public places. California anticipates extending "all the current legislation concerning tobacco products", which includes limitations on advertising, to the e-cigarette.

There is no current legislation specifically for e-cigarettes in the United Kingdom, Germany, Spain or Italy.

France prohibited sales of e-cigarettes to minors in March 2014¹⁰.

In Denmark, Finland and Sweden only electronic cigarettes without nicotine may be sold.

In reality, the risk-benefit balance for e-cigarettes taken over the population at large (i.e. smokers and non-smokers) will vary from one person to another.

One needs to differentiate between:

- the tobacco smoker who is looking to the electronic cigarette as a way to stop smoking, and for whom several developments are possible. One can imagine that this smoker:

⁹ See "The Telegraph": <http://www.telegraph.co.uk/finance/newsbysector/epic/bats/10213091/BAT-plans-to-ominate-e-cigarette-market.html>

¹⁰ Law no. 2014-344 dated 17th March 2014 published in Official Journal no. 65 of 18th March 2014.

- will cease smoking completely, both tobacco and e-cigarettes;
- will stop smoking tobacco but will become a devotee of e-cigarettes with or without nicotine;
- will become a *vapofumeur*, adding the potential risks from the electronic form to the existing tobacco-related risks;

- the non-smoker who starts with *vaping* and runs the very strong risk of becoming dependent and moving on to tobacco. This risk would be particularly high among young people.

Today, there is insufficient data available to be able to quantify the various probabilities of these transitions.

Maximum health benefits come with complete cessation of tobacco smoking. **By completely replacing** tobacco with e-cigarettes, the benefits come from the end of intoxication by tars, carcinogens and other toxic substances present in tobacco smoke. We are here in the realm of risk reduction. However, the benefits can also be real for *vapofumeurs* if the combination of tobacco and e-cigarette is simply a stage on the road to breaking the tobacco habit. The benefit is less in the case of the double smoker because, although there is a diminution of inhaling tobacco smoke, the effect of exposure time is still very much present. At the moment there is a lack of sufficient experience and data to be able to conclude the debate concerning risk reduction among the *vapofumeur* population.

Health risks concern:

- the nicotine experience (particularly with young people); the e-cigarette can be the route to addiction, but also to tobacco smoking;
- support for those with nicotine addiction;
- exposure over time to the substances contained in e-cigarettes, the long-term toxicity of which are not yet known;
- the risk of a re-normalisation of nicotine consumption which could lead to tobacco becoming once again socially more acceptable.

There is still insufficient information available for a proper assessment of the risk-benefit ratio, in particular concerning:

- the proportion of people who cease tobacco smoking as a result of using e-cigarettes and the proportion of *vapofumeurs*, as well as their respective levels of tobacco consumption. The current surveys being carried out by the OFDT and by the INPES will be able to furnish initial responses to these questions at the end of 2014.
- the degree of motivation for *vapofumeurs* to give up tobacco smoking
- etc.

As a result, the HCSP recommends:

1. **Periodic monitoring of the level and the manner of electronic cigarette usage** in the light of the lack of scientific knowledge concerning this modern method of nicotine delivery. Given the exceptionally rapid and sizeable growth in the use of electronic cigarettes by the general public, it will be important to have:
 - representative data concerning the general public's e-cigarette consumption on a biennial basis over six years, including data concerning the number of *vapofumeurs* and their level of consumption.
 - longitudinal surveys carried out particularly among adolescents to be able to understand their entry into smoking, their level of consumption, both of tobacco and e-cigarettes, and their levels of consumption or abstinence over regular periods;
 - qualitative studies concerning smokers' (of both types) motivation and the way they represent themselves;

- economic studies to be able to quantify the level of price elasticity for e-cigarettes and the effects of substitution by other tobacco-based products as well as by the traditional nicotine substitutes;
- studies of the marketing strategies adopted by these industries;
- studies on toxicity,

with the aim of having a better appreciation of the scope of any prevention policies to implement if necessary (Noel et al. 2011);

This could well be included in the health survey mechanisms covering the general population such as the Baromètre Santé by the INPES or the ESCAPAD survey run by the OFDT but could also be incorporated into the public research organisations' work - (Inserm, ITMO Santé Publique, etc.). One notes with interest certain panel studies - CONSTANCES¹¹ and E-share¹² have just added questions about e-cigarettes in their annual questionnaires to track the trends in e-cigarette consumption.

These behavioural and population related studies should enable clarifying the situation such that policy decisions can be made on a more solid basis concerning the risk-benefit ratio and the status to be granted to this new phenomenon. Is it a realistic risk-reduction tool? Is this new product a real help in cessation of tobacco consumption such that it could be considered as a medicinal product? Is it simply a new consumer product? Should nicotine be banned in e-cigarettes? Does the use of electronic cigarettes render tobacco smoking more acceptable?

Such studies must be financed and run by the public authorities and conducted using methods that leave no room to be challenged.

2. **The creation of a coordination authority** that will be able to assess trends in tobacco and e-cigarette consumption and to **define and possible regulatory and monitoring tools**. Several important questions remain to be debated:

banning smoking and *vaping* in public places. Do the mechanisms of article L. 3511-7 "It is forbidden to smoke in places designed for collective occupation¹³, particularly educational establishments and public transport, except in places specifically reserved for smokers" apply to *vaping*? The Conseil d'Etat has already been asked to deliver an interpretation of this article. If, for whatever reason, prohibiting '*vaping*' appears to be necessary (inciting school children to smoke, smoke detectors in aeroplanes, nuisance for fellow passengers in trains), the HCSP recommends that such prohibition be inserted into the internal regulations that govern the establishments concerned.

- decide whether, as in Scandinavia, to allow only e-cigarettes without nicotine to be sold, which would solve the problem of a new addiction developing in France. All things considered, it should be made mandatory to mention the nicotine concentration on the front of the packet of e-cigarettes and to insert a leaflet concerning the risks so that the consumer is fully informed of the risks he runs, in line with the latest European Directive on tobacco products.

The coordination authority should include representatives from among the users.

3. **Publicly available information for consumers concerning the risks or the ignorance of risks (HAS, 2013) in e-cigarette use**. Such information enabling an informed choice could:

- position the electronic cigarette among all the other means of cessation of tobacco smoking (nicotine substitutes sold in pharmacies, special help-line, consultations with specialists in addiction, etc.); this point is all the more important since half of e-cigarette users claim, in the month they make the choice, that breaking the tobacco habit is their objective (OFDT, 2014),
- incorporate the e-cigarette into all the arguments used in fighting addictive behaviour. Electronic cigarettes could find a useful place in a programme of breaking the tobacco habit and, thus, the medical world should be able to:

¹¹ <http://www.constances.fr/fr/> panel consisting of a representative sample of 200,000 adults aged between 18 and 69 at entry, and consultants from the Social Security's Centres d'examen de santé (CES).

¹² <http://www.i-share.fr/> concerning the health of students.

¹³ Article R. 3511-1 of this code stipulates that the ban on smoking in places designed for collective occupation applies: "1. In all closed and covered places open to the public or that constitute a place of work; 2. In public transport."

- position the e-cigarette within the range of available cessation methods, whether these are covered by the social security or not;
- differentiate all the various products (cigarettes, e-cigarettes, patches and gums) by the specific blood diffusion kinetics that characterise each product.
- have a global approach to the question of addiction not forgetting gestural addiction.

4. Communicating about:

- banning sales to minors, which has just been enacted in the law on consumption, known as the Hamon law ¹⁴, as part of the aim to limit experimentation with nicotine, and also to incorporate the e-cigarette into all the arguments used in fighting addictive behaviour.
- the risks to pregnant women of 'vaping' (and, of course, those associated with tobacco).

5. Periodic checks to be made on the presence of nicotine and its concentration, on e-liquid contents, on the compliance of contents with what is indicated on the packaging by the manufacturer, as recommended by the French national consumer council (N'Sondé, 2012) . These checks could be carried out by the national testing laboratory (there is currently in place a study of this possibility, financed by the General Directorate for Health). On this subject, the Afnor (a French standards association¹⁵) is currently working on establishing standards¹⁶ for the electronic cigarette.

6. Take steps to counter the potential re-normalisation of nicotine consumption, inhaled or smoked, among which could feature an advertising ban, in the same way as for tobacco.

7. That this current expert opinion be updated in a year's time to reflect all advances in the available knowledge in this area.

In conclusion,

Any risk-benefit analysis depends on the type of situation.

- **the risks associated with the growth of electronic cigarette consumption are: ○ the re-normalisation of tobacco ;**

○ and, for non-smokers, a beginning of nicotine addiction, with the logical possibility of becoming addicted to tobacco. This risk would seem to be particularly high among young people.

- **For smokers wishing to break the tobacco habit, the electronic cigarette is a tool in lowering the risk if cessation really does occur.**
- **For *vapofumeurs*, several questions remain unanswered and there is a need for studies to provide a solid base of information for preparing more scientifically sound recommendations.**

The principal warning from the HCSP concerns the risk of nicotine addiction among adolescents and the descent into tobacco addiction.

The Special Committee on Health Prevention, Education and Promotion met on 23rd April, 2014: 11 out of 16 voting members were present with no conflicting interests. The text was approved as follows : For - 11, abstentions - 1, against - 0.

¹⁴ Law no. 2014-344 dated 17th March 2014 published in Official Journal no. 65 of 18th March 2014.

¹⁵ Le groupe AFNOR contribue aux processus de régulation volontaire, par la prise en compte des intérêts de tous les acteurs socio-économiques soucieux d'agir en conformité avec les règles.

¹⁶ The AFNOR group contributes to voluntary regulation procedures, by taking account of the opinions and interests of all socio-economic players who are keen to act within the rules.

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