

# Impact of EU Ban on Higher Nicotine E-Cigarettes on Tobacco Smoking



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## Executive summary

The Tobacco Products Directive being considered by the European Parliament on Wednesday 26th February 2014 includes a proposed ban on all e-cigarettes containing more than 20mg/ml nicotine. According to independent research, this equates to less than 1/3 of the nicotine absorbed through tobacco smoking and some 25% of Europe's 10 million e-cigarette users currently use e-cigarettes with higher nicotine concentrations. These 2.5 million users are also typically the most heavily dependent smokers or ex-smokers. They will face a choice under this ban of using other nicotine sources (such as lower strength e-cigarettes, gum or patches), quitting through will-power alone or returning to tobacco smoking. Since weaker e-cigarettes have not satisfied this group's needs and most have failed to quit using other methods, a significant fraction may return to tobacco use.

The ban compromises e-cigarettes' role in supporting successful smoke cessation. Our forecast is that the proposed regulation will lead to 210,000 less Europeans successfully quitting smoking each year. Among smokers that are not necessarily in the process of quitting there are those who use e-cigarettes for smoking reduction. Here the effect will be a 0.8% increase in tobacco smoking or the equivalent of an extra 9.6 million cigarettes being smoked each day across the EU.

Standard mortality tables indicate that one half of long-term cigarette smokers are killed by their habit. Our forecast would therefore be that the proposed ban will result in an additional 105,000 deaths every year across Europe.

While more research is needed in this area it is clear that the data that does exist makes it very likely that a ban on such a widely used alternative to smoking tobacco will have a very serious negative impact on public health. It is the responsibility of those who support such a ban to demonstrate what evidence they have to support it.



# 1 Background

According to the most recent estimates from European Commission<sup>1</sup>, tobacco remains the single largest avoidable health risk in the EU, accounting for nearly 700 000 premature deaths each year. Around 50% of smokers die prematurely (on average 14 years earlier). Smoking prevalence in the EU is still high with an estimated 28% of the adult (15 or older) population being regular smokers<sup>2</sup>. This percentage corresponds to about 120 million individuals<sup>3 4</sup>.

Smoking cessation and smoke-related harm reduction have, therefore, a very important role to play in EU health outcomes. Devices such as e-cigarettes that deliver nicotine without the harmful effects of tobacco smoke are a crucial tool in the fight for better health.

The debate around e-cigarette regulation in Europe has been conducted with limited reference to the available evidence and little understanding of the functional uses of e-cigarettes for smokers. The intervention of scientists (see below) saying that the Commission had gravely misinterpreted their research was not welcomed. In addition, the Commission has not conducted economic modelling of the impact of any of their policies on prices and product availability and ultimately the impact this will have on the health of Europe's 10 million e-cigarette users.

This report looks at one of the most controversial aspects of the Tobacco Products Directive - the proposed ban on e-cigarettes with nicotine concentrations in excess of 20 mg/ml<sup>5</sup>. This report asks, in particular, the effect of the ban on the estimated 2.5 million e-cigarette users currently using these stronger nicotine devices across the EU.

An open letter sent to the EU by a group of scientists working on this field,<sup>6</sup> is strongly critical of this proposal:

*"The Commission quotes<sup>7</sup> Dr. Farsalinos' papers<sup>8</sup> to justify the claim that 20mg/ml of nicotine matches the average cigarette delivery. Dr. Farsalinos has written to the Commission stating that they have misinterpreted his findings. His research instead shows that 20 mg/ml e-liquid provides less than one-third of the nicotine delivered by one tobacco cigarette.<sup>9</sup> 50mg/ml is needed to roughly match a tobacco*

<sup>1</sup> [http://ec.europa.eu/health/tobacco/introduction/index\\_en.htm](http://ec.europa.eu/health/tobacco/introduction/index_en.htm)

<sup>2</sup> [http://ec.europa.eu/health/tobacco/introduction/index\\_en.htm](http://ec.europa.eu/health/tobacco/introduction/index_en.htm)

<sup>3</sup> Population 15 or older as a percentage of total, according to Eurostat

<http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&plugin=1&language=en&pcode=tps00010>

<sup>4</sup> 28% of 85% of 505 million = 120 million

<sup>5</sup> The Tobacco Products Directive proposed text includes at its Recital c) for Article 18 the following: "Nicotine containing liquid should only be allowed under this Directive where the nicotine concentration does not exceed 20 mg/ml. This level of concentration is similar to the dose of nicotine derived from a standard cigarette during the same duration of smoking."

<sup>6</sup> The letter is entitled "Scientific Errors in the Tobacco Products Directive", dated January 16, 2014, and can be found at <http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/149-tpd-errors>.

<sup>7</sup> European Commission (2013) Fact sheet on E-Cigarettes [http://ec.europa.eu/health/tobacco/docs/fs\\_ecigarettes\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/fs_ecigarettes_en.pdf)

<sup>8</sup> Farsalinos et al. Evaluation of Electronic Cigarette Use (Vaping) Topography and Estimation of Liquid Consumption. *Int J Environ Res Public Health*. 2013;10: 2500-14. And Farsalinos et al. Evaluating nicotine levels selection and patterns of electronic cigarette use in a group of 'Vapers' who had achieved complete substitution of smoking. *Substance Abuse: Research and Treatment*. 2013; 7:139-146.

<sup>9</sup> Farsalinos K. et al. Nicotine absorption from electronic cigarette use: comparison between first and new generation devices. Presented to the FDA, December 19, 2013 (submitted for publication). And Farsalinos K. et al. Nicotine absorption from electronic cigarette use: comparison between experienced and naive users. Presented to the FDA, December 19, 2013.

*cigarette. All other existing studies confirm this.<sup>10</sup> Some 20 to 30% of electronic cigarette users use liquids above 20mg.<sup>11</sup> Higher nicotine content liquids are typically used by the most dependent smokers, who have the highest risk of smoking-related damage, and who benefit most from switching to electronic cigarettes. Most such heavy smokers need more than 20mg/ml to switch from smoking to vaping.”*

Furthermore, the scientists have made clear that there is no risk of nicotine toxicity for e-cigarette users who use 50mg/ml e-cigarettes that produce similar amounts of nicotine to tobacco. Nausea stops both vapers and smokers long before toxic levels are reached.

We use the statements above as a basis for our assumption that **approximately 25% of EU e-cigarettes users use concentrations of nicotine greater than 20mg/ml.**

The uses of e-cigarettes:

In order to assess the possible impact of the proposed ban, we need first to consider the different functions that e-cigarettes may play for smokers, ex-smokers and non-smokers. Smokers may use e-cigarettes to assist them in quitting attempts or to reduce tobacco smoking. Ex-smokers may use e-cigarettes to help keep them off tobacco and because they feel the need to continue consuming nicotine. Non-smokers may use them as recreational devices.

The latter use is, according to existing evidence, extremely rare. The **Smoking Toolkit Study** estimate based on UK population surveys that only about 0.3% of non-smokers have used e-cigarettes.<sup>12</sup> We will therefore not consider this segment of e-cigarette users further.

In what follows, we make an assessment of the likely magnitude of the impacts of restricting e-cigarettes concentration to <20mg/ml on a) the rate of successful tobacco smoking cessation b) smoking reduction trends and c) motivation for quitting.

As field surveys in much of Europe are limited, we have relied on data from other researchers and surveys conducted in the UK to make inferences about the predicted effects across the EU.

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<sup>10</sup> Vansickel AR, Eissenberg T. Electronic Cigarettes: Effective Nicotine Delivery After Acute Administration. *Nicotine & Tobacco Research* 2012.

Hajek P, Goniewicz M, Phillips A, Myers-Smith K, West O, McRobbie H. Nicotine intake from electronic cigarettes and effect of practice: Report to the MHRA. London: Wolfson Institute of Preventive Medicine, Queen Mary University of London, 2013.

DawkinsL, CorcoranO. Acute electronic cigarette use: nicotine delivery and subjective effects in regular users. *Psychopharmacology (Berl)*. 2014 Jan;231(2):401-7.

Nides MA, Leischow SJ, Bhatler M, Simmons M. Nicotine Blood Levels and Short-term Smoking Reduction with an Electronic Nicotine Delivery System. *American Journal of Health Behavior* 2014; 38(2): 265-74.

<sup>11</sup> 10) DawkinsL, CorcoranO. Acute electronic cigarette use: nicotine delivery and subjective effects in regular users. *Psychopharmacology (Berl)*. 2014 Jan;231(2):401-7. And Etter, J. F. & Bullen, C. (2011) Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy, *Addiction*, 106, 2017-28.

<sup>12</sup> Trends in electronic cigarette use in England, Robert West, Jamie Brown, Emma Beard, University College London, January 2014; <http://www.smokinginengland.info/sts-documents/>; page 13.

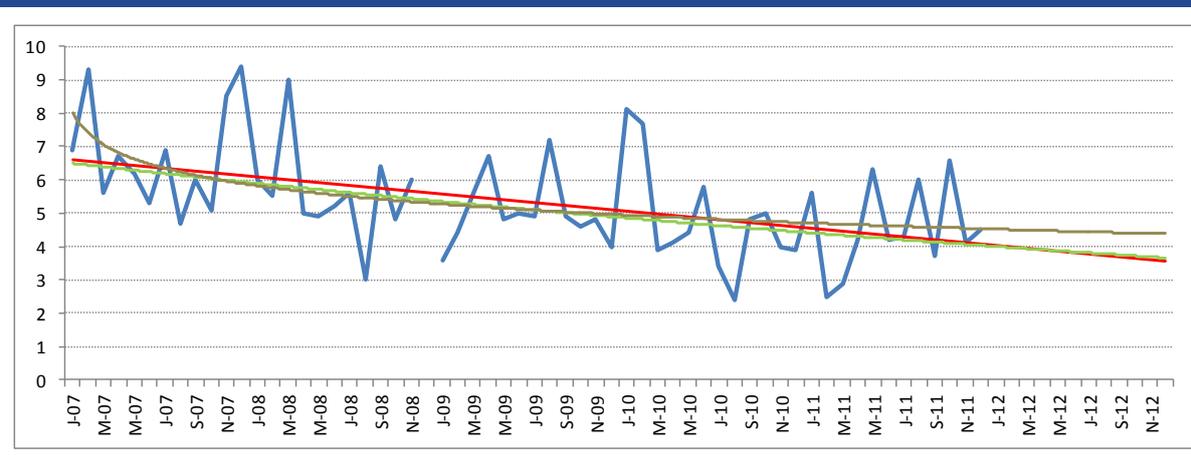
## 2 The role of e-cigarettes in smoking cessation

### 2.1 Cessation trends prior to e-cigarette market penetration

After a short-lived upturn, the years following the introduction of the UK smoking ban in 2007 saw a sharp fall in successful quitting attempts.<sup>13</sup> There is compelling evidence to suggest that that decline has been dramatically reversed by the rapid growth of e-cigarettes from 2011 with smokers becoming both more motivated and successful at quitting.

As Figure 1 below illustrates, a forecast of quitting success rates based on monthly data from 2007-2011 would point to successful quitting of between 3.5% and 5%. The graph includes three fitted trend lines – linear (red), exponential (green) and logarithmic (brown). These provide an indication of the range of forecast values that the 36 data points generate with different functional forms.

**Figure 1: Quitting success on a downward trend to end of 2011**



*Source: Analysis of trends based on data from "Key findings from the Smoking Toolkit Study"; Robert West, Jamie Brown, Jenny Fidler, University College London, 19 January 2012<sup>14</sup>*

It is therefore important to note that the period from 2012 onwards corresponds to the rapid growth in e-cigarette use as an aid to attempts to quit.

### 2.2 E-cigarettes have become the most important smoking cessation aid

In the space of little over two years, take-up of e-cigarettes has gone from almost zero to overtake all other smoking cessation aids. By observing the correlation of the evolution of the use of e-cigarettes and other methods, it is possible to make some inferences with respect to which alternatives are more readily being replaced by e-cigarettes. It is found that e-cigarette growth has the strongest negative correlation with prescription NRT (Nicotine replacement Therapy) and medicines such as Champix<sup>15</sup>. This can be interpreted as indication that e-cigarettes attract those

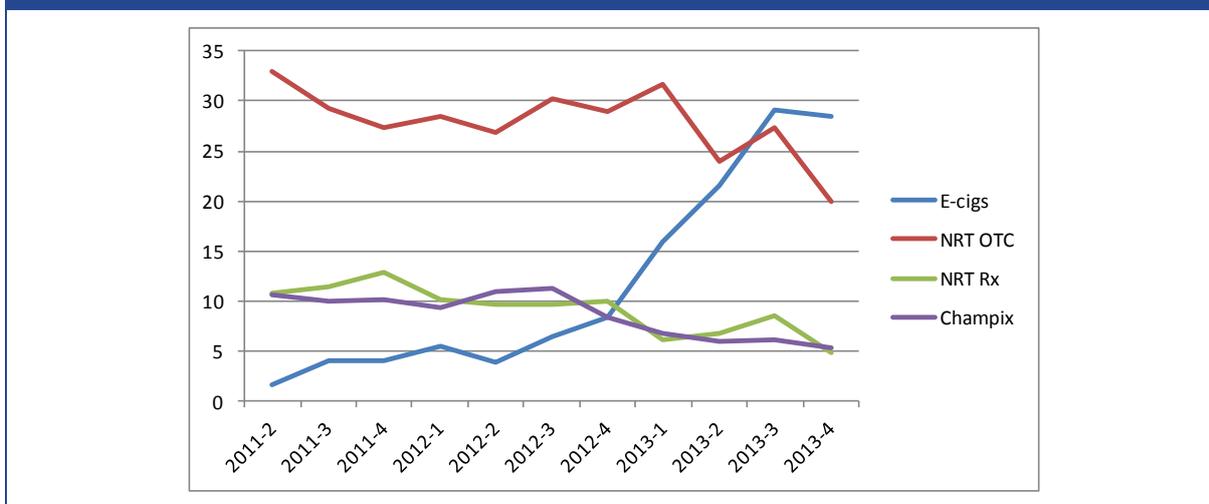
<sup>13</sup> Successful quitting is defined as having been a smoker the year before and being smoke free at response date.

<sup>14</sup> <http://www.smokinginengland.info/sts-documents/>

<sup>15</sup> Champix is one of the medicines used as smoke cessation aid, not nicotine based.

smokers who would otherwise resort to prescription methods. It is also clear from the graph that as e-cigarette use has increased at the same time that all other smoke quitting aids have declined.

**Figure 2: e-cigarettes penetration correlated with reversal of downward trend**



Source: Trends in electronic cigarette use in England, Robert West, Jamie Brown, Emma Beard, University College London, January 2014; <http://www.smokinginengland.info/sts-documents/>

It is also possible to observe a significant correlation in the data showing that quitting rates are increasing alongside the greater penetration of e-cigarettes. If we take yearly averages of the success rate in quitting attempts, we observe a strong recovery in 2012 and 2013:

Table 1: Rate of non-relapsed quitting attempts; yearly average	
2007	6.72
2008	5.58
2009	5.03
2010	4.79
2011	4.80
2012	6.25
2013	6.23

Source: Yearly average calculated based on data from Analysis of trends based on data from “Key findings from the Smoking Toolkit Study”; Robert West, Jamie Brown, Jenny Fidler, University College London, 19 January 2012 and from “Trends in electronic cigarette use in England”, Robert West, Jamie Brown, Emma Beard, University College London, January 2014; <http://www.smokinginengland.info/sts-documents/>

### 2.3 Effect of the >20mg restriction on quitting success

It is difficult to prove causality between this reversal and the rapid penetration of e-cigarettes in the quitting aids market. However, the correlation is strong and there are no other clear impacts affecting the quitting aids market in this period that could explain the effect above.

It seems reasonable, therefore, that we attribute at least a significant part of the increased rate of quitting success to e-cigarettes. Since the difference between 2012-2013 and 2010-2011 is about 1.4 percentage points, it is conservative to suggest that approximately half of the increase in

successful quitting attempts can be attributed to the increased take up of e-cigarettes (0.7 percentage points of the increase).

The proposed restriction will remove from the market e-cigarettes with >20mg/ml. Under our assumptions, about 25% of "vapers" use those higher concentrations. Therefore, 0.175% of the number of smokers in the previous year may not succeed at quitting due to the imposition of the proposed ban.

Since the number of smokers in the UK is approximately 20% of the adult population of 43 million, the magnitude of this effect is of 15,050 fewer smokers successfully quitting in a given year.

For the rest of the EU, we know that 28% of the population smoke tobacco. However, we lack reliable statistics on the penetration of e-cigarettes and therefore the calculation is more difficult to undertake. In principle, there is no reason to expect that attitudes to quitting differ markedly across Member States. While the penetration of e-cigarettes is possibly lower in some countries it is however predicted to increase rapidly so that the situation in other countries would soon become comparable to the UK's.<sup>16</sup>

Applying the same estimates to the EU, 0.175% of the population of smokers deterred from quitting corresponds to about 210,000 EU smokers that do not succeed in quitting in a given year because of the 20mg restriction.<sup>17</sup>

In sum, about 15,000 fewer UK smokers would succeed in quitting their habit in the year after the nicotine concentration regulation and the corresponding value for the EU overall, against a baseline similar to the UK's, is 210,000.

Standard mortality tables indicate that one half of long-term cigarette smokers are killed by their habit. With the users of higher nicotine e-cigarettes being more dependent smokers than their mortality would likely to be higher due to their previous exposure and future smoking levels if they relapse.

## 2.4 Alternative data source checks

In order to gain additional confidence on the orders of magnitude estimated above we considered also the results from a Redburn (2013) research paper from August 2013.<sup>18</sup>

Redburn (2013) estimate that e-cigarettes could reach 7% of the UK tobacco/nicotine market by 2017, causing an additional decline in tobacco volumes of 1.7%. Our own estimate is that this effect will not take as long although we are more conservative in terms of magnitude: we have considered only 0.7% of smoking cessation attributable to e-cigarettes.

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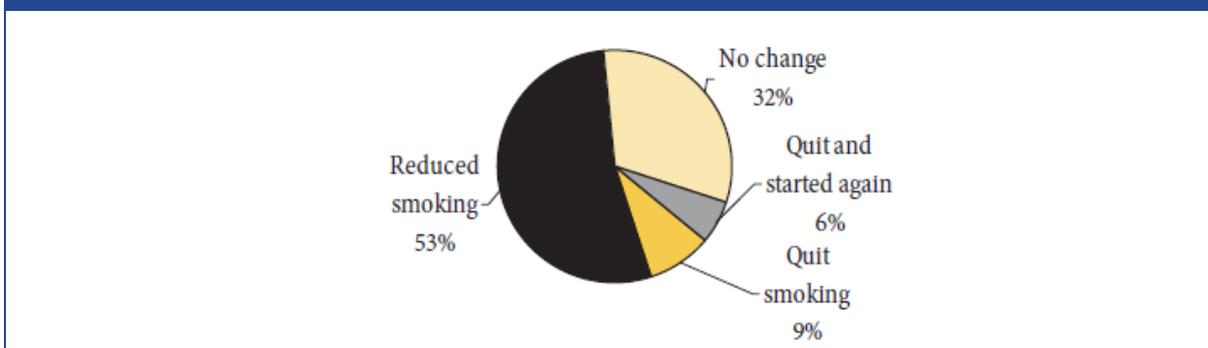
<sup>16</sup> In any case the situation with the ban should be compared to the situation with light regulation as a base case to assess the costs of regulation. And if regulation elsewhere in Europe is similar to that in the UK then we would expect penetration rates of e-cigarettes soon to converge.

<sup>17</sup> 0.175% of 120 million = 210,000; 120 million smokers across the EU28 estimated from Section 1 above.

<sup>18</sup> Christian de Roualle, Chris Pitcher, "Tobacco: Electronic Interference" Redburn, 8 August 2013

Figure 11 of their report (reproduced below) shows that 9% of smokers who tried e-cigarettes have quit smoking (and not relapsed), confirming that quitting rates are higher and quitting is more successful with the aid of e-cigarettes.

**Figure 3: Change in consumption with use of e-cigarettes, UK**



Source: Christian de Roualle, Chris Pitcher, "Tobacco: Electronic Interference" Redburn, 8 August 2013

Redburn (2013) also estimate that the impact of e-cigarette demand reduced consumption of traditional tobacco by 0.3% in 2012 and forecast that this will increase gradually to 1.7% by 2017 as the momentum remains strong from a much bigger base. This represents UK volume losses in addition to the 1-2% per year industry decline trend.

Redburn projections may be underestimates given that the monthly Smoking Toolkit Study of 1,800 UK smokers showed that e-cigarette use doubled in 2013 (Figure 2). However, as for the impact that is specifically attributable to e-cigarettes, our numbers are more conservative.

### 3 Impact of the ban on smoking reduction trends

It is clear from the table below that the market penetration of e-cigs has been contemporaneous with a significant increase in the consumption of non-tobacco nicotine by smokers.

**Table 2: Prevalence of nicotine products while smoking**

	E-cigs	NRT	All non-tobacco nicotine
2011-2	1.9	16.3	17.8
2011-3	3.2	14.3	16.2
2011-4	3.9	14.3	17.2
2012-1	5.6	12.1	17.4
2012-2	6.2	12.5	17.4
2012-3	7.5	13.3	19.7
2012-4	10.8	13.4	21.8
2013-1	15.5	9.7	23.6
2013-2	14.7	13.7	25.5
2013-3	19.1	16.2	30.9
2013-4	19.2	11.4	27.2

Source: "Trends in electronic cigarette use in England", Robert West, Jamie Brown, Emma Beard,

University College London, January 2014

About 10% more smokers use non tobacco nicotine in 2013 than in 2011, due to e-cigarettes. If we assume that these smokers receive approximately 1/3 of their nicotine needs from non-tobacco sources, then an increase of 10% of smokers doing this corresponds to 3.3% reduction in tobacco consumption.

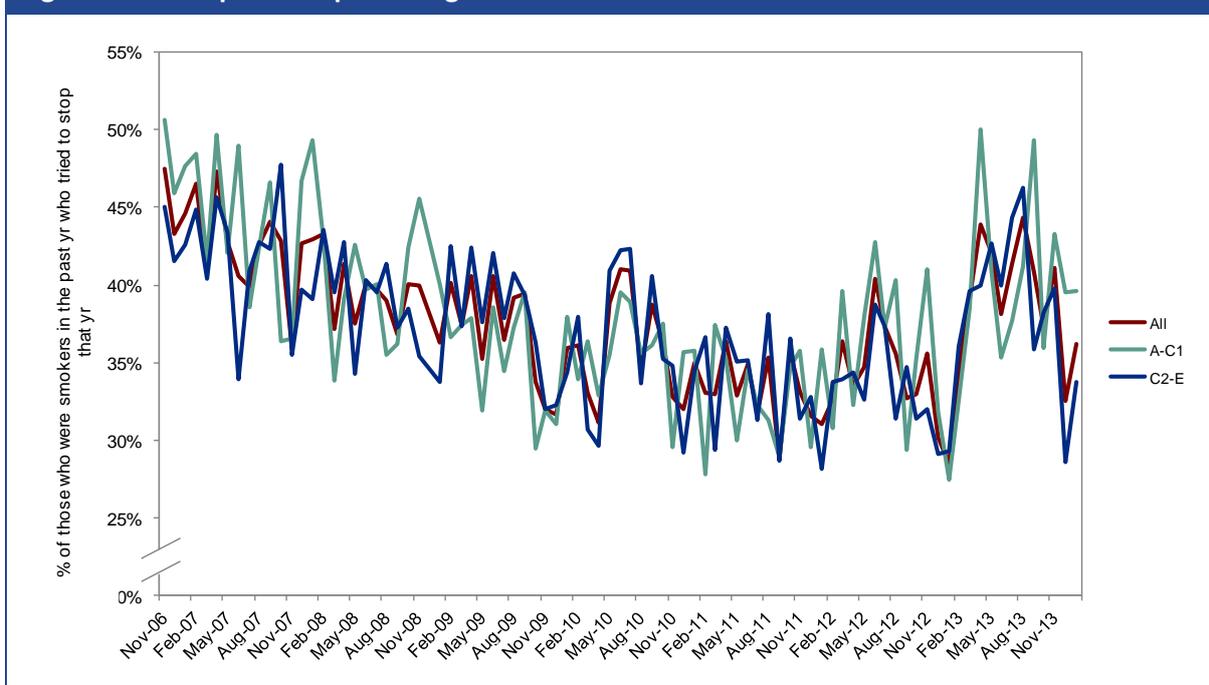
With the >20mg/ml restriction, this effect of e-cigarettes would be reduced by approximately one quarter, corresponding to the fraction of e-cigarette users that have a demand for greater concentrations. Therefore, we would estimate that approximately 0.8% more tobacco would be smoked as a result of the regulation.

If we assume that on average about 10 cigarettes are smoked per day per smoker across the EU,<sup>19</sup> the ban will result in 9.6 million more cigarettes being smoked per day by EU smokers, or 3.5 billion more cigarettes in one year.<sup>20</sup>

## 4 Effect of the >20mg ban on quitting attempts/motivation to quit

There is some indication that e-cigarettes have encouraged more smokers to attempt to quit.

Figure 4: Attempts to stop smoking



Note: A-C1: Professional to clerical, C2-E: Manual occupation

Source: "Latest trends on smoking in England from the Smoking Toolkit Study", Robert West and Jamie Brown, January 2013

<sup>19</sup> According to Eurobarometer "Attitudes of Europeans towards tobacco", May 2012, page 20, the average number of cigarettes smoked per day by EU smokers is estimated at 14.2; our assumption of 10 per day is therefore conservative.

<sup>20</sup>  $0.8\% \times 10 \text{ cigarettes per day} \times 365 \text{ days} \times 120 \text{ million EU smokers} = 3,504,000,000$

As Figure 4 indicates, there is a downward trend in quitting behaviour lasting until about end of 2011 and then a slightly more positive outlook. The temporal changes may be indicative of a perception that e-cigarettes make quitting tobacco less difficult.

The total amounts of nicotine consumed by those switching from tobacco to nicotine replacements are likely to remain constant in a first stage. The ability of e-cigarettes to deliver an adequate amount of nicotine, particularly to those accustomed to higher levels, is an important transitional advantage of these products. The first step into tobacco cessation can thus be taken with considerably less anxiety to the smoker.

Given that those for whom quitting is most difficult are also more likely to consumer higher nicotine amounts, it is to be expected that lower availability of >20mg/ml e-cigarettes will have an important negative effect on quitting attempts and motivation to quit.

## 5 Inadequate choices facing higher nicotine e-cigarette users

In sum, the 2.5 million Europeans who use the higher nicotine e-cigarettes, along with those who would have otherwise used these devices in future if the proposed regulation were introduced, face a set of alternatives none of which are particularly attractive or likely to bring about positive public health outcomes.

1. Smokers could switch to lower level nicotine e-cigarettes. For highly dependent smokers this seems unlikely given that these e-cigarettes already provide less than one third of the nicotine of a standard tobacco cigarette.
2. Smokers could move to gum and patches. However, many of these smokers will have tried these alternative approaches before without success.
3. Smokers could attempt to give up smoking unaided - though this group may have struggled with the willpower only approach.
4. Alternatively they could return to tobacco smoking which provides sufficient nicotine and, as some might argue, the hand-to-mouth and warm inhalation which attracted them to switch to e-cigarettes.
5. A final consideration, which is not considered in this report, is the development of an under-the-counter market of illegal e-cigarettes which would be subject to no regulation.

All of these choices deserve further research if policy makers want to make fully informed decisions about such a critical area for public health.

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