

Setting the parameters for a new Tobacco Products Directive

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The European Commission is asking for feedback on its Tobacco Products Directive (TPD). The call for evidence closes on 17 June 2022 and is intended to 'assess to what extent the framework has fulfilled its goals and whether it is able to support a "Tobacco-Free Generation" by 2040'. A new TPD is likely to be proposed and brought into law in the next few years.

Article 20 of the existing Directive already places unnecessary limits on nicotine strength, tank size, bottle size and advertising. There are fears that the EU will go even further and restrict or ban e-cigarette flavours (except 'tobacco' flavour) and introduce laws to restrict the sale of heated tobacco.

Nicotine regulation in the EU does not have to be a one-way ratchet, however. An evidence-based approach would see some restrictions in Article 20 relaxed, the ban on snus reversed and tobacco harm reduction embraced. The current approach is not working.

Introduction

E-cigarettes have the potential to prevent millions of early deaths in the EU in the coming decades, but surveys indicate that public understanding of the risks and benefits of vaping has become divorced from the scientific evidence. A Eurobarometer survey published in February 2021 reveals widespread ignorance and negativity towards vaping combined with low rates of e-cigarette use and stubbornly high rates of smoking.

- Of those who have little or no experience with vaping, only 20 per cent think e-cigarettes and heated tobacco products help smokers quit. Seventy per cent think they do not.
- Since 2017, the proportion of EU citizens who believe e-cigarettes are 'harmful to the health of their users' has increased from 55 per cent to 65 per cent. In 2012, the figure was just 27 per cent. The question does not quantify harm. E-cigarettes are much less harmful than smoking, but are not necessarily harmless, so people are right to answer yes to it. Nevertheless, the rise in the number of people identifying e-cigarettes as harmful may reflect an exaggerated perception of risk.

Public ignorance has serious consequences. The Eurobarometer also shows that:

- Since 2014, the smoking rate in the EU has fallen only slightly, from 26 per cent to 25 per cent.
- Between 2014 and 2020, the prevalence of current e-cigarette use remained static at two per cent of the adult population. The proportion of EU citizens who have ever tried e-cigarettes has risen only slightly, from 12 per cent in 2014 to 14 per cent in 2020.
- Thirty per cent of those who have a history of smoking and have tried using e-cigarettes or heated tobacco say that these products helped them give up smoking completely. This is twice the figure reported in the 2014 and 2017 surveys (14 per cent). Moreover, a further 27 per cent say they reduced their tobacco consumption as a result of vaping.
- Only 14 per cent of smokers say they find e-cigarettes appealing. The same proportion of smokers say they find heated tobacco products appealing.
- Less than half of the EU's long-term smokers have ever tried e-cigarettes. Among those who have smoked for more than 20 years, only 5 –18 per cent have ever tried e-cigarettes.

Smoking cessation

The evidence that vaping helps people stop smoking gets stronger every year. A study of 13,057 current and former smokers in 28 EU countries found that current e-cigarette users were almost five times more likely to have quit smoking in the last two years than non-vapers, and were more than three times more likely to have quit in the last three to five years (Farsilinos and Barbouni 2020).

The benefits of e-cigarette use in smoking cessation have been shown in a series of randomised controlled trials (RCTs), the gold standard of scientific evidence. Bullen et al. (2013), Caponnetto et al. (2013) and Adriaens (2014) all showed that smokers were more likely to quit smoking if they used e-cigarettes than if they used a placebo or nicotine replacement therapy. This was particularly impressive since two of the randomised controlled trials involved smokers who had no desire to quit at the outset.

More recently, Hayek et al. (2019) found smokers to be nearly twice as likely to quit smoking if they used e-cigarettes rather than nicotine replacement therapy. Walker et al. (2019) found that smokers using nicotine patches plus a nicotine e-cigarette were more likely to quit than those using patches plus a zero-nicotine e-cigarette.

The evidence from RCTs is consistent with evidence from observational and ecological studies. For example, a study by Zhu et al. (2017) found that the 'substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level'. A study of vape shop customers found that 41 per cent had quit smoking within a year of taking up e-cigarettes (Polosa et al. 2015). A clinical trial using second-generation e-cigarettes saw 53 per cent of subjects quit smoking (Pacifici et al. 2015).

Meanwhile, evidence from the economics literature confirms that e-cigarettes are a substitute for tobacco, not a complement or 'gateway' to it. Interventions that make vaping less attractive to consumers, such as taxes and flavours bans, have been repeatedly shown to increase cigarette consumption and smoking prevalence. Pesko et al. (2020) found that 'higher e-cigarette tax rates increase traditional cigarette use' and that an e-cigarette tax of US\$1.65 per ml would increase the number of daily smokers by one per cent. Cotti et al. (2020) studied e-cigarette taxes in eight US states and found that a decline in e-cigarette pod sales led to an increase in the sale of traditional cigarettes. Saffer et al. (2020) concluded that a large tax on e-cigarettes in Minnesota prevented 32,400 smokers from quitting.

About et al. (2019) found that e-cigarette taxes lead to more women smoking in pregnancy. Friedman (2015) found that banning the sale of e-cigarettes to minors increased the underage smoking rate by 0.9 percentage points. Dave et al. (2019) found that a ban on e-cigarette advertising reduced the number of smokers who would have quit cigarettes by three per cent. Cox et al. (2018) found that EU warnings on e-cigarette products made smokers less willing to purchase them.

Most of the economic research to date has come from the USA, but a recent study from Indonesia came to a similar conclusion. It found that following a tax on e-cigarette fluids, vapers who reported decreasing their e-cigarette use were three times more likely to report increasing their cigarette and that 'as participants reported using e-cigarettes less frequently, they reported using cigarettes more frequently' (Kowitt et al. 2022).

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Health risks

The UK's Royal College of Physicians (2016: 84) has concluded that the long-term health risks from vaping are 'unlikely to exceed 5% of those associated with smoked tobacco products and may well be substantially lower than this figure'. Many respected public health institutions around the world have come to a similar conclusion.

Nicotine is known to have a modest effect on the cardiovascular system similar to caffeine and certain foods, but there is no evidence that this poses a significant health threat to vapers, nor to users of snus¹ or nicotine replacement therapy (NRT). Several studies have found that e-cigarette users who have never smoked are at no greater risk from cardiovascular disease than never-smokers who do not vape (e.g. Osei et al. 2019, Farsalinos et al. 2019, Hayek et al. 2022).

¹ Snus is a smokeless tobacco product banned by the EU in the early 1990s due to the mistaken belief that it causes cancer (see Clarke et al. 2019).

According to a review conducted by Stephens (2018), lifetime cancer risk associated with vaping is less than one per cent of that associated with smoking.

E-cigarette flavours

In recent years, lobbying for a ban on e-cigarette flavours has become a key tactic of prohibitionists seeking to undermine tobacco harm reduction. The anti-vaping billionaire Michael Bloomberg has spent \$160 million on a global campaign to 'remove flavoured e-cigarettes from the marketplace'.² Unflavoured e-cigarette fluid is rarely used by vapers. 'Tobacco' flavour only vaguely resembles the taste of smoked tobacco and most vapers do not use it. To encourage smokers to switch to vaping, it is important to have a wide range of flavours available.

When e-cigarettes first came on the market, they were only available in tobacco flavour. The higher prevalence of tobacco flavour use among older vapers is likely to reflect, in part, the earlier initiation of the first cohort of vapers. Younger people are more likely to use flavoured juice than older people, but a majority of vapers of all ages use flavoured e-cigarettes.

Goldensen et al. (2019: 7) found that e-cigarette flavours were important to smokers looking to quit cigarettes:

Data from observational and qualitative studies suggest that flavoured e-cigarettes may aid adult smokers in smoking reduction and cessation efforts. Former smokers cite the wide variety of available flavourings and superior taste of e-cigarettes as factors that aid smoking cessation, and note that restricting the availability of flavourings would make the vaping less enjoyable and reduce the appeal of e-cigarettes.

A study by Yang et al. (2020) found that a ban on e-cigarette flavours in San Francisco led to increased smoking prevalence among 18–24 year-olds.

A study of 2,159 young adults in the USA found that 33 per cent of e-cigarette users said they would be likely to switch to cigarettes if e-cigarette flavours were restricted to tobacco flavour (Posner et al. 2022). Sure enough, cigarette sales in the USA rose in 2020 after federal restrictions on flavours in certain e-cigarette products were introduced (Maloney 2020).

'Gateway' claims

The 'gateway effect' is a term borrowed from War on Drugs rhetoric designed to encourage the prohibition of low-risk substances on the basis that their consumption inevitably leads to the use of high-risk substances. The concept remains highly controversial. Anti-vaping activists have been claiming that vaping acts as a stepping-stone to combustible tobacco consumption for at least a decade. A number of cross-sectional and longitudinal studies, mostly from the USA, have produced evidence that appears to show that young people who have vaped are more likely to have smoked. From this it is inferred that the use of e-cigarettes creates a desire to smoke.

Regardless of how many studies find an association between ever-vaping and ever-smoking, they are all flawed in the same way and any meta-analysis based on them will suffer from the problem of 'garbage in, garbage out'. The crucial missing variable is personality. The kind of person who is more likely to try an e-cigarette is the kind of person who is more likely to try a cigarette. Conversely, the kind of person who has a strong aversion to cigarettes is more likely to abstain from vaping. These personality traits are extremely difficult to control for and no researcher has found an adequate way of doing so. In the absence of sound methodology, 'gateway' studies only show that adolescents who are not risk averse will try different things and engage in risky behaviours, including vaping (Phillips 2015).

The proof the pudding is at the population level. If vaping made young people three or four times more likely to start smoking, as some studies have claimed, we should have seen a spike in youth smoking in countries where vaping is popular. In reality, e-cigarette use is associated with sharp declines in youth smoking rates and in the smoking rate overall.

After vaping became popular in England in 2012, the smoking rate fell by 20 per cent in just five years, following five years in which the rate had been almost flat. (If the UK was still in the EU, the EU's smoking rate would be 23 per cent rather than 25 per

² <https://www.bloomberg.org/press/bloomberg-philanthropies-launches-new-160-million-program-end-youth-e-cigarette-epidemic/>

cent.) In the same period, the smoking rate among children halved and is now at the lowest rate on record. Of the people in the UK who have used both cigarettes and e-cigarettes in their lives, 91.8 per cent used cigarettes first while only 0.1 per cent used e-cigarettes first (Office for National Statistics 2020).

In the USA, cigarette smoking by American high school students fell from 15.8 per cent in 2011 to 1.9 per cent in 2021 despite (or partly because of) e-cigarette use rising from 1.5 per cent to 11.3 per cent. Among American adults, the smoking rate has also dropped steeply, down from 18.1 per cent in 2012 to 12.5 per cent in 2020.

A recent study of US adolescents transiting into young adulthood found 'no evidence that initiation with e-cigarettes as the first product tried was associated with cigarette progression' (Stanton et al. 2022). A similar study of 16–24 year-olds in England found 'no association between the prevalence of e-cigarette use and ever regular smoking' (Beard et al. 2022).

What needs to be done

One of the problems with the current EU regulations is that they have removed e-cigarette fluids containing more than 20 mg/ml nicotine from the legal market. Although this has not been the subject of much academic research, it is well known in the vaping community that smokers often require a bigger nicotine 'hit' to help them switch to vaping exclusively. It is common for vapers to reduce the strength of their fluid over time, but the initial transition often demands more nicotine than EU law allows, especially for heavy smokers. There has never been a scientific justification for the 20 mg/ml cap. It is counter-productive and should be removed.

Several other EU regulations act to deter e-cigarette consumption (and therefore promote cigarette consumption). There is evidence that restrictions on e-cigarette advertising lead to fewer smokers quitting cigarettes (Dave et al. 2019) and that the health warnings on e-cigarette products mandated by the EU have made smokers less willing to purchase them (Cox et al. 2018).

Advertising restrictions should be relaxed and should focus on content rather than on the medium. There should be no objection to advertising reduced-risk nicotine products on television, radio and online if the advertisement is decent, honest and truthful. Labelling should be scientifically accurate and address genuine areas of public ignorance. As noted above, the main problem with public understanding of e-cigarettes at the moment is that people think they are more dangerous than they are. Labelling, along with government education campaigns, offers an opportunity to set the record straight.

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The restriction on bottle size (of 10ml) serves no obvious purpose, raises costs, causes inconvenience and increases consumption of single-use plastics. It should be abolished, along with the equally unnecessary restriction on tank sizes.

Current regulations ban the use of messages in and on cigarette packs which could be used to promote reduced-risk products. This law should be repealed, as should regulations that prevent sales staff from recommending safer products to consumers. Moreover, snus is banned outright despite its extremely low risk profile and its proven ability to slash the smoking rate in Sweden. The ban was introduced as a result of claims about its carcinogenic and 'gateway' potential that have turned out to be unfounded.

Readers can submit feedback to the European Commission [here](#) until 17 June 2022.

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