An Evidence-based Tobacco Products Directive

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Work is underway at the European Union to develop a third Tobacco Products Directive. This briefing outlines a number of simple measures that could be taken to improve regulation to encourage the use of reduced-risk nicotine products among smokers. Consumers are systematically misinformed about the relative risks of these products. Correcting that misinformation should be a goal of EU health policy.

The Tobacco Products Directive

The current European Union (EU) Tobacco Products Directive (TPD) was passed in 2014 and came into effect in May 2016. It applied a number of regulations to cigarettes, including graphic warnings, a ban on menthol, regulation of pack sizes, as well as controls on e-cigarettes. In the years since its implementation, there has only been a small decline in smoking prevalence across the EU. Between 2014 and 2020, the smoking rate in the EU-27 (i.e. without the UK) fell by just 1 per cent, from 26 per cent to 25 per cent (Eurobarometer 2015: 11; Eurobarometer 2021: 8).

Only two per cent of adults in the EU use e-cigarettes regularly. In the UK, where 8 per cent of adults vape, the smoking rate dropped from 22 per cent to 12 per cent between 2014 and 2020 (Eurobarometer 2015: 11; Eurobarometer 2021: 14). In Sweden, where another reduced-risk nicotine product – snus – is popular, the smoking rate was the lowest in Europe in 2020 at just 7 per cent (ibid.).

The period between 2010 and 2013, when the TPD was being developed, was a time of rapid innovation in the e-cigarette market and saw the growing popularity of vaping products. It was not until towards the end of this period that tobacco companies began to manufacture their own e-cigarettes and public health researchers began to pay attention to this category. The academic literature on vaping was relatively slim and legitimate questions about safety and efficacy were still being explored.

Since e-cigarettes do not contain tobacco, they could have easily been left out of the Directive, but once the decision was made to include them, options ranged from total prohibition to medical licensing to light–tough regulation. In the end, MEPs settled for a botched compromise in which e-cigarettes were kept on the market as consumer products but were subject to several arbitrary regulations that served no obvious purpose. These regulations were enshrined in Article 20 of the TPD.

Since 2013, strong evidence from both economics and epidemiology has shown that e-cigarettes are an effective substitute for smoked tobacco and that policy interventions designed to make vaping less attractive to consumers are associated with an increase in cigarette consumption and smoking prevalence. No serious acute risks from vaping have been identified, and the Royal College of Physicians (2019) has concluded that the long-term risks are 'unlikely to exceed 5% of the harm from smoking tobacco' We are, therefore, now in a better position to describe what an evidence-based TPD would look like.

We present ten simple, low-cost policies that could be introduced to reduce the smoking rate by getting smokers to switch to safer products.

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Fixing Article 20

Article 20 of the TPD contains some useful provisions guaranteeing the quality and safety of e-cigarettes; but it also includes several unnecessary and damaging regulations that discourage smokers from switching to vaping. A revised TPD offers an opportunity for productive reform in the following areas:

Warnings & leaflets

Under the TPD, e-cigarette products must be sold with a warning on the packaging and with a leaflet in the box informing the buyer about 'possible adverse effects' and information about 'addictiveness and toxicity'. The front and back of the box must display a warning about the 'highly addictive' nature of nicotine, covering at least 30 per cent of the surface area. Although intended for bottles of e-cigarette fluid, the legislation is so badly worded that it

mandates that atomisers and empty vape devices have to be sold with a warning that falsely states, ‘This product contains nicotine which is a highly addictive substance’.

The leaflets are unnecessary and the warnings are excessive. According to a study by Cox et al. (2018), the EU’s health warnings on e-cigarette products make smokers less willing to purchase them. Relevant information, such as advising people to keep the bottles out of reach of children, could be placed on the label instead.

Nicotine strength

The TPD imposes a limit of 20 milligrammes per millilitre (mg/ml) on the nicotine content of vape juice – that is, a concentration of no more than 2 per cent nicotine. Some smokers find that the lower-strength juice does not provide a sufficient ‘kick’ for them to want to switch permanently. In 2013, before the TPD came into effect, around a fifth of vapers consumed e-cigarette fluids with a concentration higher than 20 mg/ml (Dawkins et al. 2013). Although there is a tendency among many vapers to reduce their nicotine consumption over time, there is evidence that e-cigarettes with a relatively high nicotine content are more effective as a cessation aid for smokers who are not motivated to quit (Caponnetto et al. 2021) The current limit, which also applies to disposable cartridges, serves no purpose and is unnecessarily low. It should be dropped.

Bottle sizes

The TPD limits the size of vape juice bottles to just 10 ml. The justification for this is unknown, although it might be to reduce risk if the fluid is drunk. If so, it is not a policy that has been applied to fluids that pose a much greater risk if swallowed, such as bleach and rubbing alcohol (which, like vape juice, have to be sold in child-proof containers by law). The undesirable consequences of this regulation are the overproduction of plastic bottles, inconvenience to vapers, and higher costs for producers, which are inevitably passed on to consumers.

Tank sizes

The TPD limits the size of e-cigarette tanks (the part of refillable e-cigarettes that stores the vape juice) to 2 ml. This limit serves no purpose and merely inconveniences consumers, requiring them to refill their devices more often and carry around bottles of vape juice. It should be abolished.

Advertising

The TPD bans e-cigarette advertising on all media that can cross borders. This includes not only the internet, television and the radio, but also newspapers and magazines. E-cigarette advertising is still permitted in some media, such as billboards and at point of sale, but by restricting commercial speech, the TPD stifles competition and signals that vaping is as bad as smoking. Studies by Tuchman (2019) and Dave et al. (2019) have found that restrictions on e-cigarette advertising have led to fewer smokers quitting cigarettes. The current restrictions should be significantly relaxed, and e-cigarette advertising rules should focus on the content rather than the medium, as with alcohol.

Snus

Sweden is the only EU member state in which the sale of the smokeless tobacco product, snus, is legal, and Sweden also has the EU’s lowest smoking rate. A wealth of evidence indicates that this is no coincidence. The use of snus in Sweden is ‘associated with a reduced risk of becoming a daily smoker and an increased likelihood of stopping smoking’ (Ramström and Foulds 2006: 210). Similar findings have been reported in Norway, where snus is also legal (Lund et al. 2011).

The European Economic Community banned snus across the common market in 1992, and Sweden negotiated an exemption when it joined the EU in 1995. In response to growing epidemiological evidence of the very low risk profile of snus, the EU took the highly unusual step of removing the cancer warning from Swedish snus in 2001, and yet, the ban remains in place.

There was an opportunity to repeal the ban when the TPD was revised in 2010–2013. However, in October 2012, the EU health commissioner, John Dalli, was forced to resign after OLAF, the EU's antifraud office, accused one of his business associates of trying to solicit a €60 million bribe from the snus manufacturer, Swedish Match, in return for lifting the ban. Although there was no suggestion of wrongdoing by Swedish Match, which had reported the approach to the authorities, the scandal made snus politically toxic and the ban remained in place in the new TPD. All the scientific evidence suggests that the ban should be repealed.

Other reduced-risk nicotine products

Heated tobacco

Heated tobacco products (otherwise known as 'heat-not-burn' products) emit aerosol rather than smoke and therefore produce fewer potentially harmful compounds than cigarettes, with reductions of 50 per cent in some chemicals, and up to more than 90 per cent in others, according to the UK's Committee on Toxicity (2017). The US Food and Drug Administration has approved one heated tobacco product (IQOS) as a modified-risk product after concluding that it 'significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke' (US Food and Drug Administration 2020).

Despite this evidence, the EU has proposed a ban on flavoured heated tobacco. The TPD already bans the use of flavours in combustible tobacco products, but non-combustible tobacco and e-cigarettes are exempt. The TPD states that this exemption could be removed if there are 'market developments which constitute a substantial change in circumstance'. A substantial change is defined as an increase in sales of at least 10 per cent in any category in five or more member states. In effect, this means that if a low-risk product becomes popular, the EU will introduce regulations to make it less popular. This is evidently counterproductive and should be reviewed.

Nicotine pouches

Nicotine pouches are essentially tobacco-free snus and are believed to have an extremely low risk profile as they contain no tobacco and involve no combustion (Azzopardi et al. 2021). Since they don't contain tobacco, they can legally be sold to children under EU law. Self-regulation largely prevents this in practice, but it is a loophole that should be closed. No further regulation is required.

DG SANTE has claimed that '[m]ost Member States have called for EU level legislation that regulates these products (including banning nicotine pouches)' (Snusforumet 2022), but there is no evidence that the majority of EU countries are interested in banning these products. Some of them could do so unilaterally if they wish to, but there is no scientific justification or economic need for a ban at the EU level.

Informing the public

> The EU should send a clear message to the public about the health risks of vaping and other low-risk nicotine products relative to the risks of smoking, and this should inform policy.

Inserts in cigarette packs

Cigarette cards have not been widely used since the 1940s. Since they were generally used to promote tobacco brands, some countries have banned them on health grounds. This now seems like a missed opportunity. Inserts could be used to promote lower-risk products directly to smokers. Regulated marketing of nicotine pouches, heated tobacco, and e-cigarettes should be permitted on cigarette cards alongside evidence-based messaging from member states' health agencies.

The EU could do more to tackle the problem of misinformation. Despite abundant evidence that e-cigarettes have a very low risk profile and have helped millions of people stop smoking, scare stories regularly appear in the press and myths about e-cigarettes causing 'popcorn lung' and other diseases have proliferated on social media. An outbreak of acute lung disease, which led to dozens of deaths in the US in 2019, was misattributed to e-cigarette use and was misleadingly named 'e-cigarette or vaping use-associated lung injury' (EVALI). In actuality, the outbreak was due to people vaping illegal tetrahydrocannabinol oil adulterated with vitamin E acetate, but anti-vaping campaigners exploited the tragedy to sow fear about conventional nicotine vaping. A recent study found that this misinformation 'reduced e-cigarette demand by about 30 percent' in the US (Jin et al. 2022: 3).

Consumer ignorance is a major barrier to the consumption of low-risk nicotine products, and the hysterical claims by EU officials do not help. Vytenis Andriukaitis, the EU health commissioner between 2014 and 2019, described e-cigarettes as 'a danger to public health' (European Parliament 2016). The EU's Beating Cancer plan acknowledges that 'electronic cigarettes could allow some smokers to progressively quit smoking', but the opinion of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on e-cigarettes has been relentlessly negative, downplaying evidence that shows that e-cigarettes help people quit smoking and exaggerating potential health risks (Snowdon 2020).

Such messaging, combined with excessive health warnings and advertising bans, sends a signal to smokers that e-cigarettes should be avoided. The EU should send a clear message to the public about the health risks of vaping and other low-risk nicotine products *relative to the risks of smoking*, and this should inform policy.

Do no harm

Don't make things worse

Cigarettes and e-cigarettes are direct substitutes. As a general rule, anything that makes vaping less appealing will make smoking relatively more appealing. The EU should repeal unnecessary regulations designed to make vaping less convenient, less attractive, and more expensive (as outlined above), and it should resist calls to introduce further legislation that would have the same effects.

One of the major threats is flavour bans. There is currently a global campaign, funded by the billionaire Michael Bloomberg, aimed at encouraging governments to ban all e-cigarette flavours apart from the tobacco flavour. A handful of countries, including Finland and Hungary, have already taken this route, but the EU should not force other member states to make the same mistake.

Flavours are a fundamental part of the appeal of vaping to smokers. Goldenson et al. (2019: 106) concluded that '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 to 24 year-olds. Banning flavours is not a mild piece of regulation. For many vapers, it amounts to a de facto prohibition.

Conclusion

The EU has the opportunity to regulate e-cigarettes responsibly, achieving public health objectives while respecting personal freedom. The public understanding of the relative risks of vaping has gone backwards in recent years, and considerable work needs to be done to ensure that smokers are aware of the benefits of switching to low-risk nicotine products. Vaping is not the only safer alternative to smoking. Heated tobacco products pose less risk to health because they do not involve combustion. Snus is safer still and does not cause any form of cancer. Nicotine pouches, which resemble snus, are newer products and are assumed to be virtually risk-free since they contain no tobacco and consist mainly of cellulose.

With better education and a regulatory system that fosters innovation, many more smokers would likely switch to low-risk nicotine products, and smoking rates in the EU, which have largely stalled since the TPD was introduced, would decline significantly.

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