

# E-cigarettes and Article 20 of the Tobacco Products Directive

Christopher Snowdon, Director of Lifestyle Economics, Institute of Economic Affairs

## *What are e-cigarettes?*

Electronic cigarettes are nicotine delivery devices which use a battery and atomiser to produce vapour to be inhaled by the user. They have been commercially available for a decade and have become popular mass market products since around 2010. There are an estimated 2.6 million e-cigarette users ('vapers') in the UK, almost exclusively made up of former and current smokers. **In the EU as a whole, there are upwards of ten million current users of e-cigarettes.**

E-cigarettes are believed to be **at least 95 per cent less hazardous to health than smoking** and there is a growing body of evidence suggesting that switching to vaping is an effective method for quitting smoking.

## *What is Article 20?*

E-cigarettes are currently regulated as recreational consumer products in most EU Member States. In the UK since 2010 it has been possible to register them as medical products for smoking cessation under the authority of the Medicines and Healthcare Products Regulatory Agency (MHRA), but very few products have been submitted and only one has so far been approved. As a recent Public Health England report noted, 'regulation was described initially as 'light touch' recognising a product that delivered nicotine could be effectively used for harm reduction or cessation purposes, thus implying a relatively speedy route to licensing. This was subsequently changed to 'right touch' as it was apparent that the process was more lengthy and costly than originally envisaged'. In the UK, the process initially costs around £300,000 with an ongoing annual cost of between £65,000 and £249,000. This is beyond the reach of the vast majority of e-cigarette companies, most of which are small businesses. Since most companies (and consumers) regard e-cigarettes as recreational products rather than medicines, nearly all e-cigarettes are regulated as consumer products.

From 2016, e-cigarettes will face additional regulation under Article 20 of the EU's Tobacco Products Directive (TPD). The TPD is ostensibly designed as a market harmonisation measure to ensure the 'smooth functioning of the internal market'. In practice, many of its provisions are aimed at producing a 'high level of health protection' by reducing the appeal of tobacco products.

The Directive must be implemented by Member States by 20 May 2016.

## *Controversy*

The inclusion of e-cigarettes, which do not contain tobacco, in the TPD is controversial. In the text of the TPD, the EU states that e-cigarettes 'can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking'. However, **there is little evidence for this gateway effect**. A recent report by Public Health England notes that 'very few' nonsmokers become regular e-cigarette users. The authors of the report concluded that 'The gateway theory is ill defined and we suggest its use be abandoned'.

Clive Bates, formerly director of Action on Smoking and Health, has described Article 20 as 'a catalogue of poorly designed, disproportionate and discriminatory measures that will achieve nothing useful but do a great deal of harm'.<sup>1</sup> Given that non-smokers have so far shown little interest in e-cigarettes, critics argue that **discouraging vaping amounts to encouraging smoking** and that **some of the EU's new regulations will damage health by raising prices and reducing the appeal of products which, if smokers switched to them, would save lives**.

A legal challenge has been launched by Totally Wicked, a British e-cigarette company, on the grounds that Article 20 is 'a disproportionate impediment to the free movement of goods' and 'fails to comply with the general EU principle of equality'.

## *The regulations*

### **Limiting the size of e-cigarette fluid refill containers and devices**

Article 20	Justification
Member states must ensure that 'nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml'.	Unknown, though possibly to reduce risk if the fluid is drunk.

<sup>1</sup> <http://www.clivebates.com/?p=3026>

### Likely consequences

Limiting refill containers to 10ml, which is small by current standards, will use more resources, create more waste and reduce economies of scale for consumers. The risk of children (or adults) drinking the fluid can be reduced by making containers child-resistant. There are plenty of fluids that are hazardous if drunk, such as bleach, but few would argue that they should be sold in tiny bottles. For former smokers who have switched to e-cigarettes, smaller bottles make it more likely that they will run out of fluid when away from home, thereby increasing the likelihood of relapse.

Banning devices that can hold more than 2ml will lead to the prohibition of a large part of the current market for second and third generation devices. This will prevent consumers from using their preferred products and damage the small and medium sized businesses that manufacture and sell them. It is, however, possible that Member States will interpret this part of Article 20 to mean that devices cannot be sold with fluid already in them. This interpretation would make the legislation far less damaging.

### Limiting nicotine content in e-cigarette fluid

Article 20	Justification
Member states must ensure that 'the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml'.	To ensure that vapers do not absorb more nicotine than would be absorbed by a typical smoker.
Likely consequences	
The most commonly used fluids have a nicotine concentration of 18mg/ml, but around 20 per cent of current e-cigarette users consume e-cigarette fluid that is stronger than 20mg/ml (Dawkins et al. 2013). Some users, many of whom used to be heavy smokers of cigarettes, will find vaping unsatisfying at the lower strengths mandated by the EU, thus increasing the risk of relapse. Other heavy consumers will simply consume more fluid, thereby increasing the cost of vaping.	

### Warnings and leaflets

Article 20	Justification
Member States must ensure that 'unit packets of electronic cigarettes and refill containers include a leaflet with information on: (i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers; (ii) contra-indications; (iii) warnings for specific risk groups; (iv) possible adverse effects; (v) addictiveness and toxicity; and (vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union.'	To provide information to consumers.
Likely consequences	
Leaflets will create a large amount of waste paper to supply vapers with information that will be almost always superfluous. Pertinent information, such as advice to keep the container out of the way of children, could be easily placed on the exterior packaging and/or on the container, as with over-the-counter medicines. Other labelling, such as a warning that the product contains nicotine, can be placed on the packaging (indeed, it must be placed on the packaging under Article 20). Mandatory leafleting is bureaucratic overkill and will further inflate prices. Many suppliers do not sell bottles of fluid in boxes and will need to start manufacturing boxes just to keep leaflets in. Even tobacco products are not required to include a leaflet in every pack.	

### Provisions on refillable devices

Article 20	Justification
Member states must ensure that 'electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.'	To prevent oral consumption of a toxic substance (nicotine).
Likely consequences	
Child-proofing does not exist. The best that can be hoped for is that products will be child-resistant. Most second and third generation ('tank') devices can lose a drop or two of fluid while being refilled without any problem – as happens when filling a car with petrol. It poses no threat to health. Nicotine is a strong substance but it is heavily diluted in e-liquid. Even strong fluid only contains 20-40 milligrams of nicotine per millilitre of liquid. E-cigarette fluid would only be hazardous if consumed orally in large quantities, a risk that can be addressed with appropriate warnings and child-proofing.	
The European Commission has not yet specified what a 'mechanism that ensures refilling without leakage' is. It is not expected to make an announcement on this until the spring of 2016, ie. at the same time as the TPD comes into effect. Few, if any, such mechanisms are available on the current market. If the EU regulates with the aim of preventing any fluid ever escaping the device, it will effectively ban all, or nearly all, refillable e-cigarettes, leaving only 'cigalikes' on the market, i.e. first generation products which usually look similar to cigarettes. This would be environmentally undesirable (since cigalikes and cartridges are disposable) and would make vaping a less effective substitute for smoking (since tank devices are more effective than cigalikes). It would also guarantee a significant black market and cross-border trade with non-EU manufacturers of second and third generation devices. In the UK, these devices are the most popular type of e-cigarettes, being the preferred choice of two-thirds of vapers.	

## Consistent dose

Article 20	Justification
Member States must ensure that 'electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use'.	To ensure a reliable consumer experience.
Likely consequences	
In principle, this is reasonable but much depends on the implementation. Regulations to prevent an individual e-cigarette vapourising its fluid at wildly different and uncontrollable rates would be sensible, but there would be no benefit from setting strict limits on how much nicotine a puff of vapour could contain. Vapers, like smokers, self-regulate their nicotine intake by taking longer or shorter puffs and inhaling more or less deeply. A one-size-fits-all approach would make e-cigarettes less appealing to smokers who are thinking about switching. In any case, the testing required to prove that delivery is consistent could cost tens of thousands of euros per product.	

## Notification

Article 20	Justification
'Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date.'	Unclear, but presumably to allow the market to be monitored.
Likely consequences	
The notification regime will place a heavy cost and burden on manufacturers and retailers which will be passed on to consumers. Innovation in the e-cigarette market is very rapid at present. It is entirely possible for a product to go from new to obsolete within six months. Clearly, that will not continue under a notification regime.	

## Advertising

Article 20	Justification
'[C]ommercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers [...] any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited'. Purely domestic advertising (e.g. in cinemas and at point of sale) cannot and will not be banned by the EU.	To help prevent non-smokers and young people taking up vaping.
Likely consequences	
Advertising bans typically protect incumbents (including the cigarette industry in this instance) and reduce competition. Banning e-cigarette advertising will likely stifle innovation and may lead to higher prices. A tobacco-style prohibition on the advertising of vaping products could also give smokers the false impression that e-cigarettes are as dangerous as smoking, thus discouraging them from switching to e-cigarettes, which could save their lives.	

## Policy recommendations

As Public Health England notes, Article 20 'certainly raises the barrier for bringing [e-cigarette] products to market or continuing to market existing products, and will undoubtedly constrain the [e-cigarette] market.' Given that the vast majority of vapers are former or current smokers, barriers to entry in the e-cigarette market are disincentives to smokers who wish to switch to a much safer alternative.

**Member States have some latitude in implementing the Tobacco Products Directive. They should therefore work to mitigate the economic and health damage that Article 20 will bring about. Any 'gold-plating' by Member States, such as banning flavours, extending advertising restrictions or demanding medical regulation for vaping products, is likely to protect the incumbent nicotine industries (pharmaceutical and tobacco) against this relatively new, disruptive technology.**

## References

ASH (2015) Use of electronic cigarettes (vapourisers) among adults in Great Britain.

Brown, J., Beard, E., Kotz, D., Michie, S., and West, R. (2014) Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction* 109: doi: 10.1111/add.12623.

Dawkins, L., Turner, J., Roberts, A. and Soar, K. (2013) 'Vaping' profiles and preferences: an online survey of electronic cigarette users. *Addiction* 108(6): 1115-1125

Directive 2014/40/EU of the European Parliament and of the Council (2014) *Official Journal of the European Parliament and of the Council* L 127/1-38

Eurobarometer (2015) Attitudes of Europeans towards tobacco and electronic cigarettes. Special Eurobarometer 429

Hitchmann, S., Brose, L., Brown, J., Robson, D. and McNeill, A. (2015) Associations between e-cigarette type, frequency of use, and quitting smoking: Findings from a longitudinal online panel survey in Great Britain. *Nicotine and Tobacco Research* doi: 10.1093/ntr/ntv078

McNeill, A., Brose, L. S., Hitchman, S. C., Hajek, P., McRobbie, H. (2015) E-cigarettes: an evidence update. Public Health England.

McRobbie, H., Bullen, C., Hartmann-Boyce, J. And Hajek, P. (2014) Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? *Cochrane Database of Systematic Reviews*, 25 September