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The impact of the EU Tobacco Products Directive on e-cigarette regulation in the UK

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Introduction

In May 2016 the EU's revised Tobacco Products Directive (TPD) will come into force. This revision included many updates to regulations on tobacco products but also sets out new regulations covering e-cigarettes. The UK Government has made clear that it will not be seeking to 'gold plate' the rules coming from the EU and will implement them to create a minimum burden on business.

Many e-cigarette companies and current vapers have had concerns about these new regulations and a great deal has been written about what they will mean for the market and the products available.

This document explains the regulatory framework put in place by the EU TPD and answers some of the key concerns which have been raised about the impact of TPD implementation.

More information:

- The Tobacco and Related Products Regulations 2016
- For evidence around electronic cigarettes see the ASH briefing on electronic cigarettes
- Use of electronic cigarettes see ASH Fact sheet: Use of electronic cigarettes among adults in Great Britain;
- ASH Fact sheet: Use of electronic cigarettes among children in Great Britain
- MHRA Guidance: E-cigarettes - regulations for consumer products

What will regulation look like from 20 May 2016 onwards?

From 20 May 2016 e-cigarettes will be available for sale under EU TPD regulation.[1] There are transitional arrangements allowed by the TPD so that in the UK electronic cigarettes or refill containers which are not in compliance with the TPD can be released for sale on the UK market until 20 November 2016. From 20 May 2017 all products sold to consumers must be fully compliant with the TPD.[2]

Products which are regulated under the TPD only need to be **notified** to the appropriate regulatory authority (in the UK this will also be the MHRA). The TPD is intended to introduce harmonised standards across the EU, improve the quality of products and reduce the risk of accidents, particularly in relation to children accidently drinking liquids or products leaking. To achieve this it includes a number of standards which products must meet.

Checks will be made to ensure the notification is complete and that the information provided demonstrates that the product meets the standards set out in the Tobacco and Related Products Regulations 2016. These include:

- Child resistant/ tamper evident packaging is required for liquids and devices
- The device must be protected against breakage and leakage and capable of being refilled without leakage
- Devices must deliver a consistent dose of nicotine under normal conditions
- Tank and cartridge sizes must be no more than 2ml in volume and nicotine strengths of liquids must be no more than 20mg/ml.

Further investigation will only be undertaken, in regard to individual products, if problems are raised. Electronic cigarette batteries must already conform to UK and EU legislation which is enforced in the UK by the National Measurement and Regulation Office Enforcement Services.[3]

There will be different requirements on products depending on whether they are licensed as medicines or regulated by the TPD. Some of these are highlighted below:

	Products regulated under the EU TPD	Products regulated as medicines by MHRA
Availability	• Products widely available in all current locations • Products are not available on prescription	• Products available on general sale in the same way as paracetamol or NRT • Products can be prescribed
Advertising	• Cross border advertising banned (e.g. some print, TV and radio) • Member States can decide to regulate domestic advertising (billboards, buses etc.) Scotland is currently considering this • Can't make health claims re: helping to quit or comparisons between e-cigarettes	• Advertising allowed – under 'over the counter' medicine rules. No celebrity endorsement or free samples and must be targeted at adult smokers etc. • Can make health claims
Nicotine	No higher than 20mg/ml	MHRA regulation is flexible and product specific; there are no upper limits.
Packaging	30% health warning 'This product contains nicotine which is a highly addictive substance' on front and back of packs	No health warnings on packs
Flavours	No EU regulation on provisions Member States could choose to regulate further: no current plans in UK to introduce further controls	Flavours will be licensed as part of the authorisation process
Age of sale	Must not be sold to anyone under 18	• MHRA has power to determine age of sale for products • NRT is licenced for sale to those aged 12 and over • Current e-cigarette licence is for sale to those aged 18 and over
Device	Will have to meet standards set out in the Tobacco and Related Products Regulations 2016 and be notified to the MHRA 6 months before it is intended to place them on the market	Will have to meet manufacturing standards for medical devices and be licensed by the MHRA
Liquids	Will have to meet standards set out in the Tobacco and Related Products Regulations 2016 and be notified to the MHRA 6 months before it is intended to place them on the market	Will have to meet medicinal standards for ingredients and manufacturing and be licensed by the MHRA

Manufacturers and importers will still also be able to opt in to have products licensed as medicines.[4] There are many important differences between the two processes and that is because they are quite different forms of regulation. Products regulated as medicines go through a full authorisation process before being **licensed** by the MHRA to prove that they meet medicinal standards of safety, quality and efficacy. The MHRA has granted a licence to a novel cigarette like nicotine inhaler called Voke,[5] and, more recently, to an e-cigarette called e-voke, but neither of these products are yet on sale. The MHRA decision to grant a licence does not automatically mean that it will be available on prescription; that will be a decision for local commissioners.

Set out below are a list of concerns that have been raised about the TPD, followed by the facts.

The concern: The TPD will ban all flavours.

The facts: No. The TPD itself does not prohibit the sale of any flavours. Member States retain powers to regulate flavours if they choose and some may do so. The Directive is clear that there is value to allowing flavours: "*It could be useful for Member States to consider allowing the placing on the market of flavoured products… Any prohibition of such flavoured products would need to be justified…*". The UK Government has no current plans to go further than the TPD in this matter. As such there will be no blanket ban on flavours in the UK.

The notification process required by the TPD may have the effect of reducing the range of flavours on the market. The notification process means that manufacturers will need to tell the Government about the ingredients in each liquid, provide evidence that these ingredients meet reasonable standards of safety, and guarantee that the production process is safe. It is therefore possible that some manufacturers will choose not to notify all of their current flavours but focus on those which are most popular.

The concern: The TPD will ban all refillable tanks and variable voltage devices

The facts: No. The TPD does not prohibit any specific type of device. In principle refillable tank models could meet TPD standards.

Concerns have also been raised that variable voltage devices will not meet the standards of the TPD. However, there is nothing in the TPD to prohibit variable voltage devices.

The concern: Most products currently on the market will be removed by the TPD

The facts: As noted above some products currently on the market will need to change to meet the standards set out in the TPD. But many manufacturers have already demonstrated that they are willing and able to alter products to meet the standards.

Some current vapers may already have noticed their products evolving. For example the TPD requires that tanks be no larger than 2ml in volume and some manufacturers have started to implement this change with many making 2ml tanks available as standard. Products are being redesigned to put in place leak-proof refill mechanisms and ensure products are child resistant.

It is true that many products now available will have to change over the coming year, to meet TPD standards. However, a wide range of products will remain on the market for users to choose from.

The concern: High strengths of nicotine will no longer be available

The facts: Yes. While products licensed as medicines can be at a higher strength there will be a limit on nicotine levels for products regulated by the TPD of 20mg/ml.

For many people this will make little difference to their vaping experience as the most popular liquids tend to be those with concentrations of nicotine lower than 20mg/ml[6]. There is also evidence to suggest that devices are becoming more sophisticated and allowing people to absorb nicotine more quickly from lower concentrations, mimicking more closely the experience of smoking.[7]

We have also long known that people who are addicted to nicotine will do something called self-titrate to ensure that they get the amount of nicotine they seek.[8] This means they will use nicotine products until they get the level of nicotine they need and then stop. That is why many people when they start using an e-cigarette feel like they use it all the time compared with smoking. This is because they are seeking the same level of nicotine but it's delivered to the body in a less efficient way, so they need to use it more often than they would smoke a cigarette.

There may be a small group of people for whom the limit of 20mg/ml is insufficient. If you don't feel you're getting enough nicotine you could try using an NRT product, such as gum or patch, in addition to the e-cigarette or consider investing in a newer generation device.

Liquids with no nicotine content will not be subject to the TPD regulations or required to notify the MHRA.

The concern: Meeting new standards will reduce the performance of existing products

The facts: Most people who have been vaping for a while will have seen products evolve a great deal over the last few years and there is no indication that the pace of innovation is slowing. Indeed, newer generations of products appear to be more efficient at delivering nicotine. Meeting the new standards is likely to drive further innovation while at the same time ensuring that requirements relating to safety and reliability are met. Naturally users fear that the new standards will reduce the appeal or undermine the effectiveness of their products, but that is unlikely to be the case for most users.

The concern: No e-cigarettes will be able to meet the standards of medicines licensing

The facts: No. The first e-cigarette to be licensed as a medicine received its authorisation in November 2015.[9] It has taken some time for this product to complete the licensing process and people have understandably been concerned about this. As regulators develop greater experience of the products and manufacturers develop better understanding of what is expected of them the process should become quicker and more streamlined.

The MHRA has been clear that they will consider licensing any kind of e-cigarette, from any manufacturer, which meets medicinal standards and that they can license devices separately from liquids. There is every reason to believe that a wide range of e-cigarette type products will be able to achieve a licence as medicines, and will do so if there is a market for them.

The concern: Retailers will no longer be able to discuss products with customers

The facts: No. There is no prohibition under the TPD which would prevent retailers from discussing products with customers. There are no proposals by the UK Government that would restrict these conversations.

The TPD does restrict online advertising but not the provision of information online, nor does it prohibit the operation of online forums where individual vapers can share their experience. The Department of Health are currently developing rules on this to ensure that online retailers are still able to communicate with users about different products.

The concern: The TPD will drive small companies out of business

The facts: The e-cigarette market is a rapidly evolving one. As with many innovative disruptive technologies it started as a market with lots of small companies and a great deal of product innovation. In recent years the market has begun to consolidate with larger companies buying up smaller operations. Regulation will change the shape of the market, and it is reasonable to say that regulation often benefits larger companies with greater resources. However, it is Government policy to support small businesses, so in developing and implementing the new Regulations it is required to have regard to the specific concerns of this sector.

UK regulators have stated that they intend regulation to be 'light touch' and as such there should remain a place in the market for small as well as large companies. In January 2016 the MHRA (which will act as the UK competent authority for products regulated under the TPD) consulted on the fees that manufacturers will have to pay to notify their products under the TPD. As part of this the MHRA stressed that: "*fees passed on to business will be the minimum possible*".[10]

In April 2016 the Tobacco and Related Products Regulations 2016 were tabled and the following fees were confirmed[11]:

Initial notification fee	£150
Annual ongoing fee	£60
Modification fee	£80

There are many factors that will influence the future evolution of the e-cigarette market. Regulation is one of them but the ultimate aim of regulation is to drive up standards across a market, create a level playing field and ensure the customers get good quality products they can trust.

The concern: E-cigarettes will be regulated like tobacco products

The facts: No. E-cigarettes will not be regulated as tobacco products. There is a very wide range of regulations and legislation which apply to tobacco which will not be applied to e-cigarettes at a UK or EU level on a blanket basis. For example all advertising, promotion and sponsorship of tobacco products is prohibited, they cannot be displayed at point of sale and have high levels of excise tax, in addition to VAT, levied on them.

Some countries in the EU are considering applying some existing tobacco legislation to e-cigarettes. For example, in the UK, the Welsh Assembly is considering extending smokefree legislation to e-cigarettes and the Scottish Government is considering further restrictions on advertising. However, there is no blanket application of tobacco legislation to e-cigarettes. In England, apart from introducing an age of sale of 18, there are no current plans for the Government to go further than the TPD in regulating e-cigarettes.

The concern: There is no need for further regulation

The facts: Views vary widely both in the UK and internationally about the importance of regulating e-cigarettes and the extent to which they should be regulated. A growing number of countries are introducing complete bans on e-cigarette sales, something the UK and the EU have not supported. In the EU, during the final negotiation of the TPD, the proposal was revised from requiring medicinal licensing for nearly all e-cigarettes to one of notification with some product standards set out in the Directive.

E-cigarettes provide a potentially useful aid to help people quit smoking, but they also contain nicotine which when rapidly delivered is highly addictive, and poor quality products can carry risks in terms of their safety and effectiveness. The regulations are designed to address these concerns.

Regulation is also an important part of reassuring current non-users about the relative safety of e-cigarettes. While there are already 2.6 million regular e-cigarette users in Great Britain there are closer to 9 million smokers. Regulation should reassure those smokers who have not yet chosen to make the switch because of concerns over product quality, and help encourage them to do so.

References

1 Revision of the Tobacco Products Directive. European Commission, March 2014
2 Revision of the Tobacco Products Directive. European Commission, March 2014. See Article 30 in particular on transitional arrangements.
3 UK Government, 2015. Placing batteries on the market: producer responsibility
4 Nicotine Containing Products, MHRA
5 Public Assessment Report for e-Voke 10mg and 15mg Electronic Inhaler, MHRA
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10 Regulatory fees for e-cigarettes: consultation document, MHRA, January 2016
11 The Electronic Cigarettes etc. (Fees) Regulations 2016, April 2016