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Research Briefing

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The regulation of e-cigarettes

Summary

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The new European Union Tobacco Products Directive (TPD) entered into force on 19 May 2014, revising the 2001 Directive of the same name. It introduced new regulatory controls on electronic cigarettes (e-cigarettes, sometimes referred to as 'vapes'), as well as setting out requirements on tobacco products. The UK Tobacco and Related Products Regulations 2016 implemented the TPD in full. This Commons Library Briefing Paper outlines the product requirements for e-cigarettes and identifies where national regulations have gone beyond what is in the TPD.

The briefing does not cover the environmental impact of e-cigarettes. This is addressed in the Library debate pack on the Environmental impact of disposable vapes (November 2022).

Tobacco Products Directive

The European Union Tobacco Products Directive entered into force on 19 May 2014, with the UK Tobacco and Related Products Regulations 2016 implementing the TPD in full across the UK. According to the European Commission, the TPD's aim is to "improve the functioning of the internal market for tobacco and related products while ensuring a high level of health protection for European citizens". Article 20 of the TPD introduced new regulatory controls for nicotine-containing e-cigarettes and refill containers, though it does not cover nicotine-containing products that are authorised as medicines. These controls aimed to ensure:

- minimum standards for the safety and quality of all e-cigarettes and refill containers;
- that information is provided to consumers so that they can make informed choices;
- an environment that protects children from starting to use these products.

National regulations

The TPD did not seek to harmonise rules on:

- smoke-free environments;
- domestic advertising;
- domestic sales;
- age restrictions;

- nicotine–free cigarettes;
- flavourings of e-cigarettes.

Instead, these elements could all be regulated at a domestic, rather than EU, level.

England and Wales, Northern Ireland and Scotland each introduced age restrictions on e-cigarettes that prohibit their sale to, and their purchase on behalf of, under 18s. Further details on age restrictions are set out in the Commons Library briefing on Advertising, marketing and promotion of vaping products. In 2015/16 the Welsh Government attempted to go further and introduce controls on the use of e-cigarettes in public places, though the Bill was subsequently rejected by the Welsh Assembly.

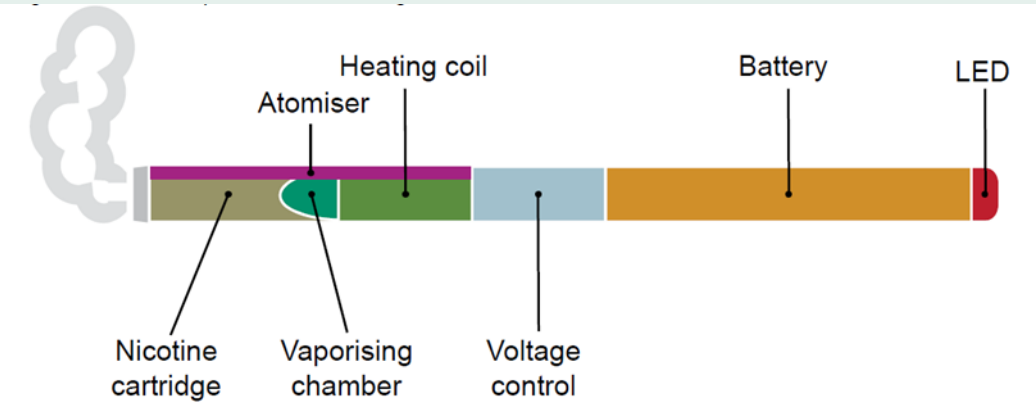
The Tobacco and Related Products Regulations 2016 were amended by the Tobacco Products and Nicotine Inhaling Products (Amendment Etc.) (EU Exit) Regulations 2019 and 2020 to enable tobacco and e-cigarette regulation to continue to function following the UK's withdrawal from the EU.

1 Background

1.1 What are electronic cigarettes?

Electronic cigarettes (also known as e-cigarettes, electronic nicotine delivery system (ENDS), or vaporisers/vapes) work by heating a solution of water, flavouring, propylene glycol (or vegetable glycerine) and, typically, nicotine to create a vapour that the user inhales. The act of using an e-cigarette is often referred to as 'vaping'. Devices tend to consist of a mouthpiece, a battery-powered heating element, a cartridge or refillable tank containing the liquid solution and an atomiser that vaporises the solution when heated.

1 The components of an e-cigarette



Source: E-cigarettes: Frequently Asked Questions (PDF), Scottish Parliament Information Centre (SPICe), November 2014

Product innovation has been rapid. In 2014, it was estimated that there were over 460 brands of e-cigarette and 7,500 flavours of solution.[1] The first generation of e-cigarettes, available from the mid-2000s onwards, tended to look like 'traditional' cigarettes and were often disposable. Second generation e-cigarettes, in contrast, were larger and not designed to resemble a cigarette. The Royal College of Physicians (RCP) note that they are "typically the size of a large fountain pen, and incorporate a more powerful battery linked to a permanent vaporiser, and a tank system that users can

[1] Zhu et al, Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tobacco Control Vol 23, iii3–iii9. 2014

refill with nicotine solution".[2] There are also 'closed systems' that cannot be modified. [3] These disposable 'ready to go vapes' come pre-filled and cannot be re-filled. Research undertaken in summer 2022 estimated that over one million disposable vapes are thrown away every week in the UK.[4]

A third generation of refillable e-cigarettes has also been developed. These are designed to be customised by the user to suit their preferences and tend to show little resemblance to a conventional cigarette.[5] Some, for example, have a more powerful battery, thereby allowing for variable voltage and adjustable air flow to alter the delivery of nicotine. Others may also include downloadable software to monitor usage and consumption via a mobile app.[6]

1.2 Prevalence of e-cigarette use in Great Britain

Figures from the Office for National Statistics (ONS) show that 9% of people aged 16 years and over in Great Britain were e-cigarette users in 2022. Most of these (5.2%) used an e-cigarette every day, while 3.5% were occasional users. This equates to around 4.5 million vapers in Great Britain.[7]

Men were more likely (9.5%) to be daily or occasional users than women (7.9%) in 2022. Usage was higher among young people, with 15.5% of people aged 16 to 24 and 10.6% of people aged 25 to 34 being daily or occasional users. [8]

For comparison, 12.9% of adults aged 18+ in the UK smoked tobacco cigarettes in 2022, though this figure varies across the UK:

- England (12.7%)
- Northern Ireland (14.0%)
- Scotland (13.9%)
- Wales (14.1%)[9]

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2 Royal College of Physicians, Nicotine without smoke. Tobacco harm reduction. A report by the Tobacco Advisory Group of the Royal College of Physicians, 28 April 2016 (PDF)

3 World Health Organization, WHO Report on the Global Tobacco Epidemic, 2021: Addressing new and emerging products, July 2021, p32

4 One million single use vapes thrown away every week contributing to the growing e-waste challenge in the UK - Material Focus, July 2022

5 DL Eaton, LY Kwan, K Stratton (eds) Public Health Consequences of E-Cigarettes, Chapter 3, E-Cigarette Devices, Uses, and Exposures, January 2018

6 National Centre for Smoking Cessation and Training (NCSCT), Electronic cigarettes: A briefing for stop smoking services, 2016, p6 (PDF)

7 Office for National Statistics, Adult smoking habits in Great Britain: 2022, September 2023

8 Office for National Statistics, Adult smoking habits in Great Britain: 2022, September 2023

9 Office for National Statistics, Adult smoking habits in Great Britain: 2022, September 2023

The proportion of vapers who are also current cigarette smokers was 27.1% in 2022. Figures from ONS show that 2.4% of people who have never smoked reported that they were daily or occasional e-cigarette users in 2022, compared to 1.5% in 2021.

Additional statistics can be found in the Commons Library briefing, Statistics on Smoking.

2 Different approaches to e-cigarette regulation

2.1 A medicine or consumer product?

The UK's approach towards regulating e-cigarettes has evolved in recent years. E-cigarettes were initially regulated as consumer products and were subject to existing product safety legislation, enforced by Trading Standards. This covered matters such as the manufacture, marketing, labelling and sale of products, as well as the electrical safety of batteries and chargers. Industry bodies have supported the consumer product approach on the grounds that e-cigarettes are neither tobacco products nor medicinal products intended to cure nicotine addiction and should not, therefore, be regulated as such.[10]

In June 2013, the UK Government decided that "all nicotine-containing products (NCPs), such as electronic cigarettes" were to be "regulated as medicines in a move to make these products safer and more effective to reduce the harms of smoking".[11] This followed research commissioned by the Medicines and Healthcare products Regulatory Agency (MHRA – the UK's medicines and medical device regulator) into the quality, safety, marketing, and use of the products, as well as an impact analysis on the consequences of regulation.

The researchers reported that "the quality of NCPs can vary considerably"[12], with levels of nicotine differing "from what was listed on the label and from batch to batch". They added that NCPs were "often poorly manufactured, containing contaminants and with leaks of nicotine from the cartridges".[13] The MHRA concluded that "licensing [NCPs] as medicines [would] allow people to have the confidence that they are safe, are of the right quality and work".[14]

A similar approach was initially proposed by the European Council in a revision of the 2001 Tobacco Products Directive (Directive 2001/37/EC). Noting

10 Electronic Cigarette Industry Trade Association, Response to Welsh Public Health White Paper, June 2014

11 MHRA, Press release: UK moves towards safe and effective electronic cigarettes and other nicotine-containing products, 12 June 2013

12 MHRA, Press release: UK moves towards safe and effective electronic cigarettes and other nicotine-containing products, 12 June 2013

13 I Torjesen, E-cigarettes are to be regulated as medicines from 2016, BMJ 2013;346:f3859

14 MHRA, Press release: UK moves towards safe and effective electronic cigarettes and other nicotine-containing products, 12 June 2013

that Member States had "so far taken different regulatory approaches to address these products", the Council proposed in 2012 that:

> Nicotine containing products that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance.[15]

This was subsequently revised in 2013 when the European Commission proposed a more restrictive change whereby all e-cigarettes would have been subject to pharmaceutical regulation, regardless of their nicotine content; an approach later rejected by the European Parliament.[16] The final version of the Tobacco Products Directive ((2014/40/EU) discussed in detail below) allows e-cigarettes to be marketed without a medicines licence if the nicotine concentration does not exceed 20mg/ml. This superseded the MHRA's 2013 plans to regulate all e-cigarettes as medicines, so the MHRA's proposals were not taken forward.

2.2 International approaches

Regulation of e-cigarettes and vaping products varies internationally. The Global State of Tobacco Harm Reduction (GSTHR) provides a country-by-country summary on the use, availability and regulations applying to vaping products, snus (oral tobacco) and heated tobacco products. It collates and analyses information available from a range of published sources.[17]

Some countries, including Brazil and Singapore, have adopted neither a medicine nor consumer product approach to regulation, instead issuing an outright ban on the sale, distribution and importation of e-cigarettes.[18] The WHO reported in 2021 that "32 countries currently ban ENDS [electronic nicotine delivery systems]".[19]

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15 European Commission, Proposal for a Directive Of The European Parliament And Of The Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (explanatory memorandum), December 2012

16 D Saitta et al, Achieving appropriate regulations for electronic cigarettes, Therapeutic Advances in Chronic Disease, (2014) Vol 5, pp50-61

17 GSTHR is run by Knowledge Action Change (KAC), a company focused on the promotion of harm reduction to improve health, and funded by the Foundation for a Smoke-Free World Inc. This foundation is an independent US non-profit.

18 World Health Organization, WHO Report on the Global Tobacco Epidemic, Country Profile: Brazil, 2015 (PDF); World Health Organization, WHO Report on the Global Tobacco Epidemic, Country Profile: Singapore, 2015

19 World Health Organization, WHO Report on the Global Tobacco Epidemic, 2021: Addressing new and emerging products, July 2021, p42

In Australia, for example, it has been illegal to possess, supply or sell nicotine-containing e-cigarettes since October 2021 except when they are being supplied or accessed through a prescription. Imports of nicotine-containing e-cigarettes are also restricted to those with valid prescriptions.[20] The British Medical Journal, however, reported that despite the change in law in 2021, "vape shops have proliferated across [Australia] [...] selling disposable vapes in a variety of colours and flavours which, studies suggest, are likely to contain unlabelled nicotine".[21]

The Federal Government in Australia has since gone further and, in May 2023, proposed "stronger regulation and enforcement of all e-cigarettes, including new controls on their importation, contents and packaging", such as:

- stopping the import of non-prescription vapes;
- increasing the minimum quality standards for vapes including by restricting flavours, colours, and other ingredients;
- requiring pharmaceutical-like packaging;
- reducing the allowed nicotine concentrations and volumes; and
- banning all single use, disposable vapes.[22]

The Australian federal health minister described the steps as an important part of the Government's efforts to "shut down a major health risk to the youngest generation of Australians".[23]

Other countries, including Malta, regulate e-cigarettes as tobacco products, meaning that they cannot be advertised, they cannot be used in enclosed public spaces, and they can only be used by adults over the age of 18.[24] Some countries – including Cambodia, Jordan, Nepal, Panama, Syrian Arab Republic, Thailand, Turkmenistan and United Arab Emirates – have gone further and banned the use of e-cigarettes in their entirety.[25]

20 Australian Department of Health and Aged Care, About e-cigarettes, last updated 13 April 2023
21 Australia bans all vapes except on prescription to stem use in children | The BMJ, May 2023
22 Taking action on smoking and vaping | Health Portfolio Ministers and Aged Care, 2 May 2023
23 Australia bans all vapes except on prescription to stem use in children | The BMJ, May 2023
24 R D Kennedy et al. Global approaches to regulating electronic cigarettes, Tobacco Control, November 2016, 26 440-445 (PDF)
25 A McNeill et al, Vaping in England: an evidence update February 2019 A report commissioned by Public Health England, February 2019, p24 (PDF)

3 EU Tobacco Products Directive

3.1 Overview

The European Union Tobacco Products Directive (TPD) (2014/40/EU) entered into force on 19 May 2014. The TPD repealed and replaced Directive 2001/37/EC which did not cover e-cigarettes. Article 20 of the new regulations, however, set out the requirements for e-cigarettes and refill containers for the first time. The UK Tobacco and Related Products Regulations 2016 ("the Tobacco Regulations") implemented the TPD in the UK in full and came into force on 20 May 2016.[26] Although the Tobacco Regulations apply throughout the UK, devolved nations could choose to apply greater restrictions and, in some instances, have done so. National regulations are discussed below (see section 4).

The Tobacco Regulations set out new requirements and administrative provisions on the manufacture, presentation and sale of tobacco and related products, including e-cigarettes. The European Commission explained that the aim of the TPD was to "improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens".[27] Key changes include:

- introducing larger and mandatory pictorial health warnings covering 65% of cigarette packaging;
- a ban on "characterising flavours", such as menthol and vanilla, that conceal the smell and taste of tobacco;
- the introduction of EU-wide tracking and tracing from 2019 to combat the trade of illicit tobacco products and;
- a ban on selling cigarettes in packs of less than 20.

The Tobacco Regulations apply to all tobacco products manufactured from 20 May 2016; however, under transitional arrangements, the UK and other Member States allowed manufacturers an additional 12 months to sell old

[26] The subject matter of the legislation is largely reserved and concerns harmonising of trade. The Department of Health, therefore, agreed to transpose the TPD on behalf of the Devolved Administrations in Scotland, Wales and Northern Ireland.

[27] European Commission, Revision of the Tobacco Products Directive, May 2016

stock. From 20 May 2017, however, all tobacco and related products covered by the Directive must be fully compliant.[28]

3.2 The Tobacco Products Directive and e-cigarettes

Article 20 of the TPD introduced new regulatory controls for nicotine-containing electronic cigarettes and refill containers. The TPD does not cover nicotine-containing products that are authorised as medicines. In its guidance on the TPD and e-cigarettes, the government stated that the Tobacco Regulations aim to ensure:

- minimum standards for the safety and quality of all e-cigarettes and refill containers (otherwise known as e-liquids);
- that information is provided to consumers so that they can make informed choices;
- an environment that protects children from starting to use these products.[29]

Product requirements for e-cigarettes under the TPD and Tobacco Regulations

The new requirements for e-cigarettes set out in the TPD, and implemented in the UK by the Tobacco Regulations, cover product standards and nicotine strength; safety; labelling and packaging, notification and vigilance; advertising and annual reporting. These are set out below:

a) Product standards and nicotine strength

- e-cigarette tanks are limited to a capacity of no more than 2ml;
- the maximum volume of e-liquid for sale in one refill container is restricted to 10ml;
- e-liquids are limited to a nicotine strength of no more than 20mg/ml;
- certain ingredients/additives including colourings, caffeine and taurine are banned;
- nicotine doses should be delivered by e-cigarettes at consistent levels under normal conditions of use.

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28 An additional transitional period did exist for some products. For example, the prohibition of menthol flavour in cigarettes came into effect on 20th May 2020.

29 Medicines and Healthcare products Regulatory Agency, E-cigarettes: regulations for consumer products, 29 February 2016, last updated November 2022

b) Safety

e-cigarettes and refill products must be:

- child-resistant and tamper evident;
- protected against breakage and leakage;
- e-cigarettes and refill products must have a mechanism that ensures refilling without leakage (unless it is a disposable e-cigarette);
- standards for ensuring refilling without leakage are set out in section 36(10) of the Tobacco and Related Products Regulations 2016.

c) Labelling and packaging

New labelling and warning requirements include:

- stating all substances contained in the product, and information on the product's nicotine strength, on the label;
- displaying instructions for use, information on addictiveness, and toxicity on the packaging and accompanying information leaflet. This should include a reference that the product is not recommended for use by young people and non-smokers, as well as warnings for specific risk groups and possible adverse effects;
- a health warning covering 30% of the surfaces of the unit packet and any outside packaging stating "This product contains nicotine which is a highly addictive substance."

d) Notification and vigilance

- all e-cigarettes and e-liquids are required to be notified to MHRA before they can be sold. Producers of new, or substantially modified, e-cigarette and refill container products must submit a notification to the MHRA six months before they intend to put their product on the UK market;
- a producer of electronic cigarettes or refill containers must establish and maintain a system for collecting information about all of the suspected adverse effects on human health of the product.

e) Advertising

- advertising or promotion (directly or indirectly) of e-cigarettes and refill containers in print media, on the radio and television is prohibited;
- promotional elements are not allowed on e-cigarette packaging and cross-border advertising and promotion of e-cigarettes is prohibited.

f) Annual reporting requirements

- Manufacturers and importers of electronic cigarettes and refill containers will have to submit, annually, to the Secretary of State:
  - comprehensive data on sales volumes, by brand name and type of the product;
  - information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
  - the mode of sale of the products; and
  - executive summaries of any market surveys carried out in respect of the above. [30]

3.3 What is not covered by the Tobacco Products Directive?

The TPD does not harmonise rules on:

- smoke-free environments;
- domestic advertising (the situation on advertising is complex, however, and is discussed in further detail in section 3.4);
- domestic sales arrangements;
- age limits for electronic cigarettes or refill containers;
- nicotine-free e-cigarettes;
- flavourings of e-cigarettes.

Instead, Member States were free to regulate such matters within the remit of their own jurisdiction and encouraged to do so in the Directive.[31] The UK Government indicated that it was not seeking to go above and beyond what was already in the TPD.[32] For example, in October 2016 the government stated that it had "no further plans to ban or restrict the sale of flavoured e-

30 Medicines and Healthcare products Regulatory Agency, E-cigarettes: regulations for consumer products, 29 February 2016, last updated November 2022; ASH, Countdown to 20th May 2016: Changes to tobacco regulations, May 2016; ASH, The impact of the EU Tobacco Products Directive on e-cigarette regulation in the UK, April 2016; Council Directive 2014/40/EU, OJ L 127, 3 April 2014

31 Council Directive 2014/40/EU, OJ L 127, 3 April 2014

32 Department of Health et al, Government response to the consultation on implementation of the revised Tobacco Products Directive (2014/40/EU), January 2016 (PDF)

cigarettes in England"[33] and reiterated this point in November 2018.[34] Similarly, the government stated that it had "no current plans to extend smoke-free legislation to e-cigarettes or smokeless tobacco products".[35] Totally Wicked, a supplier of e-cigarettes and e-liquid, commented in January 2016 that "the UK often gold plate EU legislation, but with this one [the TPD], they seem to be bending over backwards not to".[36]

3.4 Support for the Tobacco Products Directive

Health organisations and professionals have broadly supported the TPD. Commenting after the text of the TPD was agreed in December 2013, the tobacco control charity ASH (Action on Smoking and Health) referred to it as a:

> a tremendously important day for public health. ASH congratulates all those who have worked so hard to ensure the Directive stayed on track to get the best possible health outcomes. This is a triumph of public health over the vested interests of the tobacco industry which tried but failed to derail the Directive.[37]

The Royal College of Nursing stated that it supported "the final text of the Tobacco Products Directive" and called on "the UK Government to transpose the legislation into national law as soon as possible"[38], while Cancer Research UK emphasised that the TPD would set "standards on tobacco which will bring real benefits for people's health in the UK and across Europe".[39]

Some health organisations wanted the TPD to go further. The Government Response to its consultation on the implementation of the 2014 TPD highlighted that:

> Many health respondents were encouraging of further, tougher action on tobacco products – urging for more stringent legislation, recouping of costs from the industry and bringing in legislation as soon as possible.[40]

3.5 Opposition to the Tobacco Products Directive

There have been several legal challenges to the EU Tobacco Products Directive. Of particular relevance to this briefing is a case brought by Pillbox

33 PQ 48248 [on Electronic Cigarettes: Sales], 18 October 2016
34 HL Deb, 13 November 2018, c1780
35 PQ 48250 [on Electronic Cigarettes], 18 October 2016
36 'The TPD Consultation and room to wriggle', Vaped by Totally Wicked, 20 January 2016
37 ASH, EU Tobacco Products Directive: agreement reached, 18 December 2013 (page now offline)
38 Royal College of Nursing, Tobacco Products Directive (2014/40/EU) RCN Briefing, May 2014 (PDF)
39 'Tough EU smoking rules approved', BBC News Online, 26 February 2014
40 Department of Health et al, Government response to the consultation on implementation of the revised Tobacco Products Directive (2014/40/EU), January 2016, p15 (PDF)

38 (UK) Limited (which trades under the name 'Totally Wicked') relating to the new rules on electronic cigarettes contained in Article 20 of the Directive. The case was initially heard by the High Court of Justice (England and Wales) before being referred to the Court of Justice of the European Union (CJEU) for a preliminary ruling.[41] Totally Wicked explained that its challenge was based on its view that:

> Article 20 of the TPD represents a disproportionate impediment to the free movement of goods and the free provision of services, places electronic cigarettes at an unjustified competitive disadvantage to tobacco products, fails to comply with the general EU principle of equality, and breaches the fundamental rights of electronic cigarette manufacturers.[42]

It added that the Directive sought to bring:

> e-cigarettes and e-liquid within its [the TPDs] regulatory scope as "tobacco related products" – despite not containing tobacco – and subject e-cigarettes to more stringent regulation than some conventional tobacco products.[43]

Cases were also brought by Philip Morris International (PMI) and British American Tobacco (BAT), and by the Republic of Poland. PMI and BAT questioned whether several provisions in the TPD – including the standardisation of the labelling and packaging of tobacco products – were valid, while Poland opposed the prohibition of menthol cigarettes.[44]

The Opinion of the Advocate General, Juliane Kokott, was delivered in December 2015 and addressed all of the TPD cases. She concluded that the new EU Tobacco Directive was lawfully adopted. In relation to e-cigarettes, Advocate General Kokott stated that the rules in Article 20 "differ appreciably in several respects from the rules for conventional tobacco products", were "relatively moderate, both in comparison with the rules for conventional tobacco products and by international standards" and were "ultimately not disproportionate".[45] Though an Advocate General's Opinion is not binding, the CJEUs final judgment, delivered on 4 May 2016, concurred with the Opinion.

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41 A national court can ask the CJEU for 'preliminary rulings' when it is in doubt about the interpretation or validity of an EU law and is seeking clarification. Case-law of the Court of Justice of the European Union, Case C-477/14 Pillbox 38 (UK) Ltd, 4 May 2016

42 'European Court rules in totally wicked legal challenge to Article 20 of the Tobacco Products Directive', Vaped by Totally Wicked, 4 May 2016

43 'European Court rules in totally wicked legal challenge to Article 20 of the Tobacco Products Directive', Vaped by Totally Wicked, 4 May 2016

44 Case-law of the Court of Justice of the European Union, C-547/14 - Philip Morris Brands and Others, 4 May 2016; Case-law of the Court of Justice of the European Union, Case C-358/14 Republic of Poland, 4 May 2016

45 Court of Justice of the European Union, PRESS RELEASE No 154/15: "Advocate General Kokott considers the new EU tobacco directive of 2014 to be valid", 23 December 2015 (PDF); Opinion Of Advocate General Kokott delivered on 23 December 2015, Case C-477/14 Pillbox 38 (UK) Limited v The Secretary of State for Health

The Directive as a whole was judged to be lawful by the Court, including the provisions in Article 20.[46]

Challenge in the House of Lords

Six days after the CJEU's judgement, the House of Lords debated in Grand Committee a 'motion to take note' of the Tobacco and Related Products Regulations 2016, moved by Viscount Ridley. He stressed from the outset that he had "no problem with most of the regulations—just the parts relating to e-cigarettes and vaping".[47] Viscount Ridley described vaping as "a public health triumph that the Department of Health [had], to its extreme shame, done its utmost to block". He went on to encourage the government to "have a quick rethink and try to alter the implementation of the directive", adding that there was a "statutory instrument before us, about a third of which is devoted to stifling an exciting innovation that is saving lives".[48] The focus on e-cigarettes, rather than other aspects of the Regulations, continued throughout the debate.[49]

Responding for the government, Lord Prior, then the Parliamentary Under-Secretary of State in the Department of Health, emphasised that the government was "in favour of [vaping] as a means for people to come off smoking cigarettes" and that the question, therefore, was not about "whether we are in favour of vaping or not" but rather was "about what kind of regulation should be around it". Lord Prior subsequently clarified that:

> The intention of the regulations is to make vaping safer and less variable than it currently is. The intention of the directive is to make it a better product and to cause more people to use it. If it does indeed result in smokers not giving up smoking, then it will have achieved the reverse of what the Government wish to do. The Government's view is clear: we wish people to quit altogether but if, as a way of quitting, they can give up smoking and take up vaping, that is something that we wish to encourage.[50]

Following the debate, on 19 May 2016, Lord Callanan moved a prayer motion to annul the Regulations on the grounds that some of the proposed restrictions on e-cigarettes ran counter to advice from the Royal College of Physicians and could "force vapers back to smoking".[51] On the 8 June 2016, however, Lord Callanan amended his motion to one of regret, rather than annulment.[52]

A debate followed on 4 July 2016. Responding for the government, Lord Prior reiterated his earlier point that there was "no doubt that vaping is far better for you than smoking". He went on to make three further points. First that

46 Case-law of the Court of Justice of the European Union, Union, Case C-477/14 Pillbox 38 (UK) Ltd, 4 May 2016
47 HL Deb, 10 May 2016 c61GC
48 HL Deb, 10 May 2016, c64GC
49 HL Deb, 10 May 2016
50 HL Deb, 10 May 2016 c77GC
51 House of Lords Business, Motions relating to Delegated Legislation, Lord Callanan, 19 May 2016
52 House of Lords Business, Motions relating to Delegated Legislation, Lord Callanan, 8 June 2016

restrictions on advertising e-cigarettes formed part of "a precautionary approach to managing any risk that e-cigarettes renormalise smoking behaviours". Second, that the "regulations provide minimum product standards and reporting of ingredients and emissions" which, in turn, "should reassure smokers who are looking to quit that e-cigarettes are safe and high quality". Third, that the "UK's approach to the regulation of e-cigarettes has, and will remain, pragmatic and evidence-based". After over 90 minutes of discussion, the motion was subsequently withdrawn by Lord Callanan.[53]

In the House of Commons, Anne Main MP applied to the Speaker on 8 June 2016 for an emergency debate on the Tobacco and Related Products Regulations on the grounds that:

> The tobacco regulations will have a huge impact on the vaping and harm-reduction products industry if these regulations pass beyond their praying date of 15 June, yet the House will not have had an opportunity to debate this important matter.[54]

The Speaker stated that he had "listened carefully to the hon. Lady's application" but that he was "not persuaded that this matter is proper to be discussed under Standing Order No. 24" and an emergency debate was not held in the Commons. [55]

3.6 Reviewing the Tobacco Products Directive

Under Article 28 of the Directive, the European Commission is required to report on the application of the Directive, including any elements that should be "reviewed or adapted in the light of scientific and technical developments".[56] The Tobacco Products Directive: 2021 Application Report was published on 20 May 2021. The UK was still considered, and referred to, as a Member State for the purposes of the report.

Two main areas were identified in the report where improvements were needed: enforcement of the Directive at national level and better consideration of new market developments, such as novel tobacco products.[57]

Regarding e-cigarettes, the report concluded that some provisions in the TPD could be further developed or clarified, such as "tank size or labelling requirements; use of flavours; use of nicotine-free liquids; and advertising provisions". It added that where e-cigarettes are being used as smoking

53 HL Deb, 4 July 2016, c1831
54 HC Deb 8 June 2016 c1205
55 HC Deb 8 June 2016 c1206
56 Council Directive 2014/40/EU, OJ L 127, 3 April 2014
57 Public Health: EU Tobacco Products Directive is delivering but stronger action is needed, Press Release, European Commission, 20 May 2021

cessation aids, "their regulation should follow the pharmaceutical legislation".[58]

Review of the Tobacco and Related Products Regulations 2016

The Department of Health and Social Care also had a statutory duty to review the regulatory impact of the Tobacco and Related Products Regulations 2016 by May 2021 and publish a report setting out the conclusions of the review.[59] This is known as a post implementation review (PIR). Previous to this, the government announced in its Tobacco Control Plan, published in July 2017, that it would:

> assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context.[60]

The government later clarified that its assessment of the TPD, as it applies to e-cigarettes, would include reviewing the:

- 20mg/ml maximum nicotine refill limit,
- a size restriction of 2ml on the tank,
- a block on advertising e-cigarettes' relative harm-reduction potential and
- the notification scheme for e-cigarette ingredients.[61]

As part of the review, the Department for Health and Social Care (DHSC) held a consultation from 29 January 2021 to 19 March 2021 seeking views on how well the TRPR [Tobacco and Related Products Regulations] (and the Standardised Packaging of Tobacco Products Regulations 2015 (SPoT), which do not apply to e-cigarettes) were achieving their objectives and whether those objectives remained appropriate.

The final report, published in March 2022 (PDF), concluded that the 2016 Regulations "should remain in force based on the evidence reviewed" and that they had "met their original objectives". The DHSC added, however, the government would "consider further regulatory reforms to TRPR as part of its

58 Report from the Commission to The European Parliament, The Council, The European Economic And Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products, 20 May 2021

59 Written evidence submitted by the Department of Health (England) (ECG0030) to the House of Commons Science and Technology Committee inquiry into e-cigarettes, March 2018, para 18 (PDF)

60 Department of Health and Social Care, Towards a Smokefree Generation A Tobacco Control Plan for England, July 2017, p27 (PDF)

61 Department of Health and Social Care, The Government Response to the Science and Technology Committee's Seventh Report of the Session 2017-19 on E-cigarettes, December 2018, Cm 9738, p10 (PDF)

plans towards meeting its Smokefree 2030 ambition, and to protect future generations from the harms of tobacco".

3.7 EU withdrawal

Two sets of regulations were made – in 2019 and 2020 –that amended the Tobacco and Related Products Regulations 2016 in relation to the UK's EU exit.

Tobacco Products and Nicotine Inhaling Products (Amendment Etc.) (EU Exit) Regulations 2019

Initially, the Tobacco Products and Nicotine Inhaling Products (Amendment Etc.) (EU Exit) Regulations 2019 amended several pieces of UK legislation, including the Tobacco and Related Products Regulations 2016, to enable tobacco regulation to continue to function following the UK's withdrawal from the EU. These included measures to allow for the establishment of new notification systems for producers placing tobacco products and e-cigarettes on the market in the UK.

The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020

The government subsequently introduced new regulations - The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 - to ensure that the UK met its obligations in relation to tobacco control and vaping products under the European Union (Withdrawal Agreement) Act 2020.

Under the 2020 regulations, the new notification system for tobacco products and e-cigarettes (set out in the 2019 regulations) would be used for the GB market only; the MHRA noted that "producers placing products on the Northern Ireland market will be required to notify using the EU Common Entry Gate (EU-CEG) system for the notification of tobacco and e-cigarette products".[62] Thus, since January 2021, producers placing vaping products in the Great Britain market have been required to notify to the MHRA.

The 2020 regulations also ensure that fees are only paid once when products are notified to both the EU and GB databases.

More information is available at: Advice for retailers of e-cigarettes and nicotine-containing e-liquids (PDF) and E-cigarettes: regulations for consumer products.

[62] MHRA, E-cigarettes: regulations for consumer products, February 2016, last updated November 2022

4 National Regulations

In addition to the provisions introduced by the UK Tobacco and Related Products Regulations 2016, the devolved executives have taken steps to address the sale of e-cigarettes to under 18s. An attempt was also made by the Welsh Government to extend smokefree legislation to nicotine products, while some organisations and businesses have already restricted the use of e-cigarettes on their premises.

4.1 Age restrictions for e-cigarettes

England and Wales

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 apply to nicotine products, like e-cigarettes. Regulation 2 makes the proxy purchasing of nicotine products an offence, while Regulation 3 prohibits the sale of nicotine inhaling products to persons under the age of 18. It is also important to emphasise that the Regulations do not apply to vaping products that do not contain nicotine; non-nicotine containing vaping products fall under the General Product Safety Regulations 2005. These are enforced by local authority Trading Standards.

Scotland

Restrictions on e-cigarettes in Scotland were introduced under the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016, which came into force on 1 April 2017. The Act brought Scotland in line with England and Wales by making it an offence to sell "a nicotine vapour product to a person under the age of 18" and to "knowingly [buy or attempt] to buy a nicotine vapour product on behalf of a person under the age of 18".

Northern Ireland

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations (Northern Ireland) 2021 came into operation on 1 February 2022. The regulations prohibit the sale of nicotine products to those aged under 18 years. They also make it an offence for an adult to purchase a nicotine inhaling product on behalf of a child under the age of 18.

Further information on vaping and age of sale regulations is set out in the Commons Library briefing on Advertising, marketing and promotion of vaping products.

4.2 Use of e-cigarettes in public places

There is currently no national legislation restricting the use of e-cigarettes in public places. Smoke-free legislation, introduced under the Health Act 2006 and enacted through a series of regulations across the devolved parts of the UK, prohibits smoking in enclosed public places and workplaces, on public transport, and in vehicles used for work.[63] Further details can be found in the House of Commons Library Briefing Paper on 'Smoking in public places'.

Under Section 1(2)(a) of the Health Act 2006 "smoking" refers to "smoking tobacco or anything which contains tobacco, or smoking any other substance". E-cigarettes do not burn tobacco and do not produce smoke. The use of e-cigarettes therefore falls outside of the scope of current smoke-free legislation.

Attempts to introduce controls on the use of e-cigarettes in public places were made by the Welsh Government in 2015/16. Part 2 of the Public Health (Wales) Bill proposed restricting the use of nicotine inhaling devices in enclosed and substantially enclosed public and work places, thereby bringing the use of these devices in line with existing provisions on smoking. The Bill was ultimately rejected: a vote by the Assembly to pass the final text of the Bill in March 2016 was tied at 26-26. The Presiding Officer then exercised their casting vote and voted against the motion.[64] A new Public Health (Wales) Bill 2016 was introduced in November 2016, though earlier proposals to restrict the use of e-cigarettes in public places were not included.

In England, the government said in July 2023 that it was "exploring" vaping in public places as part of its youth vaping consultation.[65] The matter was not explicitly covered in the more recent Creating a smokefree generation and tackling youth vaping consultation, which closed on 6 December 2023.

Employers can choose whether or not to allow employees to use e-cigarettes at work.[66] Some organisations – including councils, hospitals and schools – and businesses (such as train companies and restaurants) have also prohibited the use of e-cigarettes on their premises.

Guidance on developing policies on the use of e-cigarettes in public places and workplaces has been produced by both ASH and Public Health England (PHE). PHE aimed to make its guide "non-prescriptive" on the grounds that "no one-size-fits-all answer exists to the issue of e-cigarette use in public places and workplaces" and instead sets out 5 key principles to consider:

1. Make clear the distinction between vaping and smoking.

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63 These include Smoke Free Premises etc. (Wales) Regulations 2007, Prohibition of Smoking in Certain Premises (Scotland) Regulations 2006 and The Smoking (Northern Ireland) Order 2006.

64 Welsh Assembly, Stage 4 of the Public Health (Wales) Bill, "Decisions", 16 March 2016

65 PQ 191609 [on Electronic Cigarettes] 4 July 2023

66 ASH, Will you permit or prohibit electronic cigarette use on your premises?, October 2015

2. Ensure policies are informed by the evidence on health risks to bystanders.

3. Identify and manage risks of uptake by children and young people.

4. Support smokers to stop smoking and stay smokefree.

5. Support compliance with smokefree law and policies. [67]

Similarly, ASH published the following 'tips' when formulating a workplace policy on nicotine containing products:

- Be clear about what you are trying to achieve, especially on how you are intending to improve the situation.
- Be clear about precisely what you are prohibiting –electronic cigarettes, things that could be confused with cigarettes, or both.
- Make sure your policy is good for health, by helping and not hindering smokers to reduce the harm caused by smoking to themselves and others.
- Consider the part that your policy can play in 'renormalising' or 'denormalising' the smokefree environment and promoting the right role models to children.[68]

4.3 E-cigarette advertising

Under the TPD, cross-border advertising of e-cigarettes through several media channels, including radio, television and print media, is prohibited. The TPD, however, does not cover domestic advertising, such as billboards.

Further information on e-cigarette advertising can be found in the Commons Library briefings on:

- Shop displays of tobacco and vaping products and;
- Advertising, marketing and promotion of vaping products

67 Public Health England, Use of e-cigarettes in public places and workplaces Advice to inform evidence-based policy making, July 2016 (PDF)

68 ASH, Will you permit or prohibit electronic cigarette use on your premises?, October 2015

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