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STATUTORY INSTRUMENTS

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**2016 No. 521**

**CONSUMER PROTECTION  
FEES AND CHARGES**

**The Electronic Cigarettes etc. (Fees) Regulations 2016**

<i>Made</i>	- - - -	<i>20th April 2016</i>
<i>Laid before Parliament</i>		<i>25th April 2016</i>
<i>Coming into force</i>	- -	<i>20th May 2016</i>

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(1) and section 56(1) of the Finance Act 1973(2).

The Secretary of State has been designated for the purpose of section 2(2) of the European Communities Act 1972 in relation to nicotine and nicotine products(3).

The Treasury has consented to the making of these Regulations as required by section 56 of the Finance Act 1973.

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the Electronic Cigarettes etc. (Fees) Regulations 2016 and shall come into force on 20th May 2016.

(2) In these Regulations, “the 2016 Regulations” means the Tobacco and Related Products Regulations 2016(4).

**Notification fee**

2.—(1) A fee is payable in respect of each notification submitted to the Secretary of State under regulation 31(1) of the 2016 Regulations (notification about electronic cigarettes and refill containers).

(2) The amount of the fee payable is £150 except where the notification under regulation 31(1) of the 2016 Regulations is submitted pursuant to regulation 31(2) of the 2016 Regulations (substantially modified products) in which case the amount is £80.

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(1) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7).  
(2) 1973 c.51. Section 56(1) was amended by article 6(1)(e) of the Treaty of Lisbon (Changes of Terminology) Order 2011 (S.I. 2011/1043).  
(3) S.I. 2014/2705.  
(4) S.I. 2016/507.

(3) The fee is payable at the time the notification is submitted.

(4) The fee is payable by the person submitting the notification and is payable to the Secretary of State.

#### **Annual Fee**

**3.—**(1) An annual fee is payable in respect of each product notified under regulation 31(1) of the 2016 Regulations.

(2) The amount of the annual fee payable is £60.

(3) The annual fee is payable each year on 1st April.

(4) The annual fee is first payable on the first occurring 1st April after the day the product is notified to the Secretary of State.

(5) The fee is payable by the person who submitted the notification and is payable to the Secretary of State.

(6) The annual fee ceases to be payable if the Secretary of State is notified under regulation 31(7) of the 2016 Regulations that the product has been withdrawn from the market; but any annual fee payable prior to the day the Secretary of State is notified remains payable.

#### **Adjustment of Fee**

**4.** If, after a notification fee under regulation 2 has been paid, it becomes apparent that—

(a) a lesser fee should have been paid, the excess shall be refunded to the person who paid the fee; or

(b) a higher fee should have been paid, the balance shall become payable by the person who paid the fee within fourteen days commencing with the day that the Secretary of State issues written notice to that person of the correct fee payable.

#### **Civil proceedings to recover unpaid fees**

**5.** All unpaid sums due by way of any fees payable under these Regulations shall be recoverable as debts due to the Crown.

Signed by authority of the Secretary of State for Health.

20th April 2016

20th April 2016

*George Freeman*  
Parliamentary Under-Secretary of State,  
Department of Health  
*Mel Stride*  
*George Hollingbery*  
Two of the Lords Commissioners of Her  
Majesty's Treasury

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations impose fees on producers of electronic cigarettes and refill containers.

The Tobacco Products Directive 2014<sup>(5)</sup> (see Title III) places a requirement on the producers of electronic cigarettes and refill containers to notify the national competent authority (NCA) before placing such products on their market. The Directive also imposes a requirement on the Member States to make the notified information publicly available on a website, and empowers Member States to carry out certain supervisory functions with regard to electronic cigarettes and refill containers. In the United Kingdom, these NCA and Member State functions are to be carried out by the Secretary of State for Health (acting by the Medicines and Healthcare Products Regulatory Agency (the MHRA)). This is set out in Part 6 of the Tobacco and Related Products Regulations 2016 which transposes the Tobacco Products Directive in relation to electronic cigarettes and refill containers.

These Regulations supplement the Tobacco and Related Products Regulations 2016 by introducing fees to recover the MHRA's costs. Regulation 2 creates a notification fee to cover the costs of administering the notification scheme. Regulation 3 creates an annual fee to cover the on-going costs of maintaining a website on which notification information is published and carrying out any supervisory activities. Regulation 4 allows for adjustments where the wrong fee is paid under regulation 2. Regulation 5 makes provision to enable recovery of any unpaid fees.

A full impact assessment of the effects that this instrument will have on the costs of business and the voluntary sector is available from the MHRA, 151 Buckingham Palace Road, London, SW1W 9SZ and is published with the explanatory memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

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(5) [Directive 2014/40/EU](#) of the European Parliament and 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. OJ L 127, 29.4.2014, p.1 as amended by Commission Delegated [Directive 2014/109/EU](#), OJ L 360, 17.12.2014.