
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(1) (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.

(1) [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.