

**EXPLANATORY MEMORANDUM TO**  
**THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
**TRADING FUND (AMENDMENT) ORDER 2016**

**2016 No. 549**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare Products Regulatory Agency (“MHRA”), an executive agency of the Department of Health, and is laid before the House of Commons by Command of Her Majesty.
- 1.2 This memorandum contains information for the Select Committee on Statutory Instruments.

**2. Purpose of the instrument**

- 2.1 The instrument amends the statutory terms of the MHRA’s trading fund to enable the MHRA to fund its regulatory work in relation to electronic cigarettes through its fee income.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Select Committee on Statutory Instruments*

- 3.1 The intention is to bring this affirmative instrument in to force on the day after it is made. The JCSI has previously criticised an affirmative instrument which came into force the day after making (see the JCSI’s 1st Report of Session 2013-14). However, we believe that that criticism does not apply here because the JCSI noted the offending instrument “significantly diminishes the legal rights of persons affected, or imposes new duties on such persons which are significantly more onerous than before, and requires them to adopt different patterns of behaviour accordingly”; whereas this instrument makes a technical accounting change and has no direct impact on third parties.

*Other matters of interest to the House of Commons*

- 3.2 Disregarding minor or consequential changes, the territorial application of this instrument includes Scotland and Northern Ireland.

**4. Legislative Context**

- 4.1 The Government Trading Funds Act 1973 (the 1973 Act) enables Ministers to provide that certain services provided by Government Departments, including regulatory services, may be financed by means of a trading fund. The operations financed by a trading fund must be managed so that the revenue of the fund consists principally of payment for goods or services and is sufficient to meet expenditure on the relevant operations.
- 4.2 The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (“the MHRA Trading Fund Order”), which was made under the 1973 Act, established the MHRA as a trading fund and sets out the operations covered by the MHRA trading fund.

- 4.3 This instrument amends the MHRA Trading Fund Order to add to the list of work that is financed by the trading fund. Specifically, this instrument amends Schedule 1 to the MHRA Trading Fund Order to add regulatory work in connection with the electronic cigarettes to the list of “funded operations”.
- 4.4 The regulatory work that the MHRA is to undertake in relation to electronic cigarettes is new work, arising under Article 20 of the EU Tobacco Products Directive 2014 (electronic cigarettes). The MHRA is to carry out the functions of the national competent authority and Member State under that provision on behalf of the Secretary of State for Health.

## **5. Extent and Territorial Application**

- 5.1 This instrument extends to all of the United Kingdom.
- 5.2 This instrument applies to all of the United Kingdom.

## **6. European Convention on Human Rights**

- 6.1 George Freeman MP has made the following statement regarding Human Rights:  
“In my view the provisions of the Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2016 are compatible with the Convention rights.”

## **7. Policy background**

### *What is being done and why*

- 7.1 The revised EU Tobacco Products Directive will require producers of e-cigarettes to provide a notification to the designated Competent Authority in any Member State where they wish to market their products. In the UK the Competent Authority function will be carried out by the regulatory centre of the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Secretary of State for Health. This Statutory Instrument amends MHRA’s Trading Fund Order to enable it to fund this work through fee income.

### *Consolidation*

- 7.2 There are no plans to consolidate the MHRA Trading Fund Order at this time.

## **8. Consultation outcome**

- 8.1 The Minister did not consider that it was appropriate to consult on this technical accounting change having already determined that the MHRA will take on the new regulatory work in relation to electronic cigarettes on a self-funding basis. This instrument effects the necessary technical change to the MHRA’s trading fund arrangements to enable that to happen.
- 8.2 (A consultation was carried out by the MHRA on the proposed imposition of fees in connection with the regulatory work on electronic cigarettes that the MHRA will undertake. Those fees are being introduced through a separate instrument and the consultation outcome is discussed in the explanatory memorandum accompanying that instrument.)

**9. Guidance**

9.1 This is a technical Government accounting measure. No guidance is required.

**10. Impact**

10.1 There is no impact on business, charities, or voluntary bodies.

10.2 There is no impact on the public sector.

10.3 An Impact Assessment has not been prepared for this instrument.

**11. Regulating small business**

11.1 The instrument does not apply to activities that are undertaken by small businesses.

**12. Monitoring & review**

12.1 The terms of the Trading Fund Order are reviewed in line with any new functional requirements upon the MHRA.

**13. Contact**

13.1 Caroline Robson Singh at the MHRA, Telephone: 0203 080 6299 or email: [caroline.singh@mhra.gsi.gov.uk](mailto:caroline.singh@mhra.gsi.gov.uk) is the point of contact for any queries regarding the instrument.