

EXPLANATORY MEMORANDUM TO
THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
TRADING FUND (REVOCATION) ORDER 2022

2022 No. 90

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (“DHSC”) and is laid before the House of Commons by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 This instrument dissolves the Medicines and Healthcare products Regulatory Agency (“MHRA”) trading fund. MHRA will no longer be funded by means of a trading fund and the financial arrangements of MHRA will no longer be separated from central government finances.
- 2.2 MHRA will remain an Executive Agency sponsored by DHSC.

3. Matters of special interest to Parliament

Matters of special interest to the Select Committee on Statutory Instruments

- 3.1 None.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is the United Kingdom.
- 4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

- 5.1 As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 The Government Trading Funds Act 1973 established a framework within which trading funds may be established by Order. A trading fund is a means of financing revenue-generating operations of a Government department. Income from charges made for the provision of goods and services is retained and used to meet the fund’s expenditure.
- 6.2 The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (“the 2003 Order”) established a trading fund for the operations of MHRA.
- 6.3 This instrument revokes the 2003 Order. It also revokes any Orders or provisions that will become spent when the 2003 Order is revoked.

7. Policy background

What is being done and why?

- 7.1 MHRA is an Executive Agency of DHSC. MHRA was established on 1 April 2003 following the merger of those parts of the Department of Health known respectively as the Medicines Control Agency and the Medical Devices Agency prior to that date. These two bodies are no longer operational.
- 7.2 In 2019, the Office for National Statistics undertook a review of the sector classification of MHRA, at the request of Eurostat, the Statistical Office of the European Union. The outcome of the Office for National Statistics review was that MHRA should be reclassified as Central Government with effect from 1 April 2003, the date it came into existence, meaning MHRA can no longer operate by way of trading fund.
- 7.3 The revocation of the 2003 Order will bring MHRA within DHSC's accounting boundary, meaning MHRA finances will be more closely tied to DHSC. MHRA underspends and overspends will directly impact DHSC's financial position like other arm's-length bodies within the boundary. However, MHRA will continue to fund most of its activity from its fees.
- 7.4 The revocation of the 2003 Order will have no direct effect on the services that MHRA delivers to the public.
- 7.5 This instrument closes the trading fund.
- 7.6 MHRA will remain an Executive Agency of DHSC. The purpose of Executive Agencies is to carry executive functions within government with a clear focus on delivering specified outputs.
- 7.7 Executive Agencies are governed by framework agreements, which set out in detail the division of responsibilities between the agency and the sponsoring central government department. Each agency has a Chief Executive, who is responsible for operational issues, while a Minister takes responsibility for policy decisions. The next framework agreement between MHRA and DHSC will take account of MHRA's new financial status.

8. European Union Withdrawal and Future Relationship

- 8.1 This instrument does not relate to withdrawal from the European Union or trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

- 9.1 This instrument does not consolidate any legislation and consolidation is not required for this instrument because its sole purpose is to revoke the 2003 Order and consequent spent Orders/ provisions.

10. Consultation outcome

- 10.1 In these circumstances it has not been thought necessary to undertake consultation. The revocation of the 2003 Order is a one-off change to an internal Government accounting device. This instrument will not affect the costs incurred by business. Key stakeholders, including devolved administrations, have been informed of the purpose and administrative implications of this instrument.

11. Guidance

- 11.1 There is no need for guidance on this change, as the revocation of the trading fund is a one-off change in internal government accounting for the operations of MHRA.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment has not been prepared for this instrument because trading funds are a means of financing the revenue generating operations of a government department. It is an accounting/administrative change within government and the operations of MHRA will be unaffected.

13. Regulating small business

- 13.1 This instrument does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

- 14.1 The approach to monitoring of this instrument is as follows. The revocation of the 2003 Order is a one-off change to internal government accounting for the operations of MHRA, and therefore there is no need for ongoing monitoring and review.
- 14.2 The regulation does not include a statutory review clause.

15. Contact

- 15.1 Dunia Alameddine at DHSC, telephone: 0300 790 4007 or email: dunia.alameddine@dhsc.gov.uk, can be contacted with any queries regarding the instrument.
- 15.2 Helen Lovell and Kathryn Glover, Deputy Directors for Medicines Regulation at DHSC, can confirm that this explanatory memorandum meets the required standard.
- 15.3 Lord Syed Kamall, Parliamentary Under-Secretary of State at DHSC can confirm that this explanatory memorandum meets the required standard.