**EXPLANATORY MEMORANDUM TO**

# THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (APPROPRIATION OF ADDITIONAL ASSETS AND LIABILITIES) ORDER 2014

**2014 No. 432**

**1.** This explanatory memorandum has been prepared by the Department of Health and is laid before the House of Commons by Command of Her Majesty.

## 2. Purpose of the instrument

2.1 This instrument makes provisions for additional assets and liabilities to be appropriated to the Medicines and Healthcare Products Regulatory Agency ("the MHRA") Trading Fund.

## 3. Matters of special interest to the Select Committee on Statutory Instruments

3.1 None.

## 4. Legislative Context

4.1 Up until 1st April 2013 the National Institute of Biological Standards and Control ("NIBSC") formed part of the Health Protection Agency (HPA), which was established by the Health Protection Agency Act 2004. The HPA was abolished from 1 April 2013 by section 56 of the Health and Social Care Act 2012 ("the 2012 Act"). The functions of the NIBSC, which are described in section 57 of the 2012 Act are now performed by the Medicines and Healthcare Products Regulatory Agency ("MHRA"), an Executive Agency of the Department of Health. The MHRA operates by way of a trading fund established under the Government Trading Funds Act 1973. The MHRA Trading Fund was established by the Medicines and Healthcare products Regulatory Agency Trading Fund Order 2003, as amended.

4.2 The assets and liabilities attributable to the NIBSC operations will be appropriated to the MHRA Trading Fund by this Order.

## 5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

## 6. European Convention on Human Rights

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

## 7. Policy background

- What is being done and why

7.1 As a result of the Review of Arms Length Bodies the decision was taken to abolish the HPA, of which the NIBSC formed a part. The functions of the HPA performed by the NIBSC were to be returned to the Department of Health from 1 April 2013. The Secretary of State for Health agreed that the MHRA should perform those functions.

7.2 The MHRA operates financially by way of a trading fund. A trading fund is a financing framework for Government operations, covering operating costs and receipts, capital expenditure, borrowing and net cash flow, which gives an agency greater freedom to manage its financial affairs. A trading fund retains its trading income (i.e. income generated from the provision of goods and services), which is used to meet its expenditure The functions of the NIBSC performed by the MHRA already fall within the scope of the funded operations of the MHRA contained at paragraph 1(f) of Schedule 1 the MHRA Trading Fund Order 2003. However a minor technical Order is necessary to appropriate the assets and liabilities attributable to the NIBSC functions to the MHRA Trading Fund.

- Consolidation

7.2 No instruments are being consolidated.

## 8. Consultation outcome

8.1 This Order is minor and technical in nature, with neutral cost impacts, and has therefore not been subject to consultation, in line with Cabinet Office guidance.

## 9. Guidance

9.1 No external guidance will be required as a result of this Order. The MHRA will update and amend its accounts and financial activity to incorporate the assets and liabilities of the NIBSC.

## 10. Impact

10.1 The impact on business, charities or voluntary bodies is nil – this is a transfer of functions from one Government agency to another, with no additional costs or savings to business.

10.2 The impact on the public sector is as above. The activities associated with managing the additional assets and liabilities of the NIBSC will be absorbed within the MHRA finance division's existing resources.

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

## 11. Regulating small business

11.1 The legislation does not apply to small business.

## 12. Monitoring & review

12.1 As the instrument does not amend legislation no significant monitoring or review is considered necessary. However, the operations of the NIBSC are now subject to the existing financial controls exercised in the Agency in relation to the Trading Fund, which include Treasury and NAO reporting.

## 13. Contact

**Karen Salawu** at the Medicines and Healthcare Products Regulatory Agency Tel: 020 3080 6216 or email karen.salawu@mhra.gsi.gov.uk can answer any queries regarding the instrument.