EXPLANATORY MEMORANDUM TO THE

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY TRADING FUND (AMENDMENT) ORDER 2005

2005 No. 2061

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. Description

2.1 The Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2005 amends the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, with effect from 1st September 2005, so as to –

- extend the remit of Agency's trading fund to include the Secretary of State's functions under the Blood Safety and Quality Regulations 2005 (SI 2005/50) and related EC directives on blood safety and quality; and
- restrict the remit of the trading fund, as to exclude the Department of Health's activities relating to the evaluation of medical devices.

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

3.1 None

4. Legislative Background

4.1 The following legislation is be amended by this Order: The Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (SI 2003/1076), made under the Government Trading Funds Act 1973 ("the 1973 Act"). The 1973 Act enables Ministers to provide that certain services provided by Government Departments, including the provision of authorisations and related regulatory activity, may be financed by means of trading funds. The operations financed by a trading fund must be managed so that the revenue of the fund consists principally of payments for goods or services and is sufficient to meet expenditure on the relevant operations. The 2003 Order established a trading fund to finance the operations of the Medicines and Healthcare products Regulatory Agency ("MHRA"), an executive agency of the Department of Health.

4.2 The Secretary of State for Health is exercising the powers under sections 1(1), 4A and 6(3) of the 1973 Act to extend the MHRA's funded operations (to include the Secretary of State's functions under the Blood Safety and Quality Regulations) and to restrict them (to exclude the

Department's operations relating to the evaluation of medical devices).

4.3 The Blood Safety and Quality Regulations transpose into UK law two European Blood Safety Directives: Directive 2002/98/EC which sets standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and Directive 2004/33/EC, which implements certain technical requirements of Directive 2002/98/EC.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister of State, Department of Health, Jane Kennedy, 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 2005 are compatible with the Convention rights

7. Policy background

The Blood Safety and Quality Regulations 2005

7.1 The Blood Safety and Quality Regulations 2005 (SI 2005/50) came into force on 8 February 2005; however, they will not apply fully until 8 November 2005. From that date, under the Regulations, the Secretary of State will be responsible for authorising and inspecting blood establishments, monitoring compliance of hospital blood banks and carrying out haemovigilance. The Secretary of State for Health has agreed that MHRA (an executive agency of the Department of Health) should perform those functions. It is therefore proposed that the Trading Fund Order be amended to extend the funded operations of the MHRA to include activities undertaken under the Regulations. An Explanatory Memorandum and a Regulatory Impact Assessment relating to these Regulations was laid before Parliament on 18 January 2005.

Evaluation of medical devices

7.2 The Device Evaluation Services is currently part of the MHRA and is responsible for conducting evaluations of medical devices or the components of such devices, for the NHS and other customers. The income to the trading fund provided by the DES is paid by the Department of Health.

7.3 In 2003 the Health Industry Taskforce (HITF) was established with the aim of bringing together the Government and the healthcare industry to identify opportunities to facilitate the introduction into the NHS of beneficial new technologies, whilst also helping to stimulate healthcare industry growth. Chaired jointly by Lord Warner (then Parliamentary Under Secretary of State

for the Department of Health) and Sir Christopher O'Donnell (CEO of Smith & Nephew plc), the Task Force published its findings in the report: "Better health through partnership: a programme for action", which was launched in November 2004.

7.4 One of the key recommendations of the report was "to develop a new device evaluation service to integrate and strengthen horizon scanning and the assessment of value and effective performance of new and enhanced healthcare technologies, devices and related procedures". To help effect this change HITF recommended that the existing Device Evaluation Service, currently sited in the MHRA, should move to the NHS Purchasing and Supply Agency (PaSA), an executive agency of the Department of Health that is not financed by means of a trading fund. In order for this transfer to take place, it is necessary to remove the operations of the DES from the remit of the MHRA's trading fund.

Financial impact

7.5 The movement of DES from MHRA to PaSA will have a minimal impact on the trading fund because DES is currently funded by the Department of Health. The Department will continue to provide funding in the future as customer for the services. The move will have the effect of moving the activities of DES to an agency closer to the NHS front-line.

7..6 The MHRA undertakes certain functions of the Secretary of State in respect of the Blood Safety and Quality Regulations. These functions include; authorisation, inspection, compliance monitoring and haemovigilance and are considered to be suitable, under the 1973 Act, for inclusion within the funded operations of a trading fund and therefore for funding by fees charged by the MHRA.

Consultation

7.7 The proposals to amend the Trading Fund Order were the subject of a consultation in accordance with section 1(3) of the 1973 Act. A report on the consultation has been laid before the House of Commons under section 6(4) of the 1973 Act. A copy of the report is attached.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies.

9. Contact

9.1 Mr Roy Alder at the Medicines and Healthcare products Regulatory Agency Tel: 020 7084 2600 or e-mail: Roy.Alder@mhra.gsi.gov.uk can answer any queries regarding the instrument.