Draft Order laid before the House of Commons under section 6(2) of the Government Trading Funds Act 1973, for approval by resolution of that House

DRAFT STATUTORY INSTRUMENTS

2005 No.

GOVERNMENT TRADING FUNDS

The Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2005

Made - - - -

Coming into force - - 1st September 2005

Whereas—

(1) the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**1**) established under the Government Trading Funds Act 1973 ("the 1973 Act")(**2**) a trading fund to be known as the Medicines and Healthcare Products Regulatory Agency Trading Fund ("the Fund");

(2) it appears to the Secretary of State for Health ("the Secretary of State") that—

(a) the additional operations of the Department of Health described in article 3 of this Order (being operations for which she is responsible) ("the additional operations") are suitable to be financed by means of a trading fund established under the 1973 Act and, in particular, to be so managed, in conjunction with the other operations of the Fund, so that the revenue of the Fund would consist principally of receipts in respect of goods or services provided in the course of the operations in question; and

(b) the financing of the additional operations by means of a trading fund would be in the interests of the improved efficiency and effectiveness of the management of those operations; and

(c) the operations of the Fund should be extended to include the additional operations;

(3) it appears to the Secretary of State that certain of the existing operations of the Fund are no longer suitable to be financed by means of a trading fund and should therefore cease to be operations of the Fund;

(4) in accordance with sections 1(3) and 6(4) of the 1973 Act(**3**), the Secretary of State has taken such steps as appear to her to be appropriate to give an opportunity to such persons as appear to her to be appropriate to make representations to her and has laid before Parliament a report about the representations received and her conclusions;

(**1**) S.I.2003/1076.
(**2**) 1973 c. 63.
(**3**) Section 1 of the 1973 Act was substituted by section 1(1) of the Government Trading Act 1990 (c. 30) ("the 1990 Act"); section 6(4) was substituted by section 2(3) of the 1990 Act.

(5) the Secretary of State has, in accordance with section 2 of the 1973 Act(**4**) and with the concurrence of the Treasury, determined—

(a) in relation to the additional operations, that no Crown assets or liabilities, other than those already appropriated to the Fund, are properly attributable to those operations; and

(b) in relation to the operations which are to cease to be operations of the Fund, what assets or liabilities of the Fund are properly attributable to those operations;

(6) in accordance with section 6(2) of the 1973 Act(**5**), a draft of this Order has been laid before the House of Commons and has been approved by a resolution of that House.

Now, therefore, the Secretary of State, in exercise of the powers conferred upon her by sections 1(1), 4A(2) and 6(1) of the 1973 Act(**6**), and of all other powers enabling her in that behalf, with the concurrence of the Treasury, hereby makes the following Order:—

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2005 and shall come into force on 1st September 2005.

(2) In this Order—

"device evaluation services" means services consisting of or relating to the evaluation of medical devices or similar devices, or the components of such devices, for the purpose of determining—

(i) the performance of those devices or components,

(ii) the ease with which they can be used,

(iii) whether they are suitable for use in different environments or for different purposes, or

(iv) how the safety and performance of one device or component compares with that of other devices or components intended for use for the same purpose;

"the fund" means the trading fund established by article 2 of the principal Order;

"medical device" shall have the meaning given by regulation 2(1) of the Medical Devices Regulations 2002(**7**); and

"the principal Order" means the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003.

Amendment of article 1 of the principal Order

2. In article 1 of the principal Order (citation, commencement and interpretation)—

(a) in paragraph (2), after the definition of "the 1968 Act", insert the following definition—

""device evaluation services" means services consisting of or relating to the evaluation of medical devices or similar devices, or the components of such devices, for the purpose of determining—

(i) the performance of those devices or components,

(ii) the ease with which they can be used,

(**4**) Section 2 of the 1973 Act was substituted by section 1(1) of the 1990 Act.
(**5**) Section 6(2) was substituted by section 2(3) of the 1990 Act
(**6**) Section 1 of the 1973 Act was substituted by section 1(1) of the 1990 Act; section 4A was inserted by section 1(2) of the 1990 Act; and section 6(1) was substituted by section 2(3) of the 1990 Act.
(**7**) S.I. 2002/618, to which there are amendments not relevant to this instrument.

(iii) whether they are suitable for use in different environments or for different purposes, or,

(iv) how the safety and performance of one device or component compares with that of other devices or components intended for use for the same purpose;";and

(b) in paragraph (3), for "or the Medical Devices Regulations 2002" substitute "the Medical Devices Regulations 2002 or the Blood Safety and Quality Regulations 2005(**8**)".

Amendment of Schedule 1 to the principal Order

3. In Schedule 1 to the principal Order (funded operations), in paragraph 1—

(a) after sub-paragraph (b), insert the following sub-paragraph—

"(bb) the functions of the Secretary of State under—

(i) the Blood Safety and Quality Regulations 2005, and

(ii) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(**9**) and related implementing legislation;"; and

(b) in sub-paragraph (f)—

(i) for the words from "the provision of services" to "products or devices" substitute—

"the provision of services relating to or in connection with public health, standards of quality and safety for human blood and blood components, medicinal products, medical devices or similar products or devices, other than the provision of device evaluation services," , and

(ii) omit paragraph (v).

Assets and liabilities

4. The assets and liabilities set out in the Schedule shall cease to be assets and liabilities of the Fund.

Signed by authority of the Secretary of State for Health

Minister of State,
Department of Health

(**8**) S.I. 2005/50.
(**9**) OJNo. L33, 8.2.2003, p.30.

We concur

Name
Name
Two of the Lords' Commissioners of Her Majesty’s Treasury

SCHEDULE Article 4

ASSETS AND LIABILITIES CEASING TO BE THOSE OF THE FUND

PART 1

ASSETS

1. Plant and equipment (including computers) which at 1st September 2005 are used or allocated for use in the provision of device evaluation services.

2. Data and computer software which as at 1st September 2005 are used or allocated for use in the provision of device evaluation services.

3. Intangible assets, including intellectual property, arising from the provision of device evaluation services as carried on up to 1st September 2005.

4. Debtors and cash as at 1st September 2005 used or allocated for use in, or arising from, the provision of device evaluation services.

PART 2

LIABILITIES

1. Fees paid in advance in respect of device evaluation services to be rendered on or after 1st September 2005.

2. Creditors, accruals and provisions as at 1st September 2005 arising from the provision of device evaluation services.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order varies the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 ("principal Order") so as to both extend and restrict the operations for which the Medicines and Healthcare Products Regulatory Agency Trading Fund ("the Fund") is established.

The operations are extended to include operations relating to Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components ("the Blood Directive"); in particular the functions of the Secretary of State under the Blood Safety and Quality Regulations 2005, which implement that Directive.

The operations are restricted to exclude the operations of the Department of Health relating to the provision of device evaluation services.

Article 2 of the Order amends the interpretation provisions of the principal Order. Article 3 amends Schedule 1 to the principal Order, which sets out the operations of the Fund. Article 3(a) and (b) extends the funded operations to include functions relating to the Blood Directive and the safety

and quality of human blood. Article 3(b) also restricts the funded operations so as to exclude the provision of device evaluation services.

Article 4 provides that the assets and liabilities set out in the Schedule, which the Secretary of State for Health has, with the concurrence of the Treasury, determined to be properly attributable to provision of device evaluation services (the operations ceasing to be funded), shall cease to be assets and liabilities of the Fund.

This Order does not impose any charge on business.