STATUTORY INSTRUMENTS

2005 No. 2061

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

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(**1**); 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,

(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

(**1**) S.I. 2002/618, to which there are amendments not relevant to this instrument.

(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(**2**)".

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(**3**) 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

Jane Kennedy
Minister of State,
21st July 2005 Department of Health

We concur

Dave Watts
Gillian Merron
Two of the Lords' Commissioners of Her
21st July 2005 Majesty's Treasury

(**2**) S.I. 2005/50.
(**3**) OJNo. L33, 8.2.2003, p.30.