STATUTORY INSTRUMENTS

2018 No. 1112

EXITING THE EUROPEAN UNION
GOVERNMENT TRADING FUNDS

The Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) (EU Exit) Order 2018

Made - - - - 23rd October 2018

Coming into force in accordance with article 1

The Secretary of State for Health and Social Care, with the concurrence of the Treasury, makes this Order in exercise of the powers conferred by sections 1(1) and 6(1) of the Government Trading Funds Act 1973(**1**) (the 1973 Act).

It appears to the Secretary of State that the operations of the Department of Health and Social Care covered by this Order are suitable to be financed by means of the fund established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**2**) (the Fund) and, in particular, to be so managed that the revenue of the Fund would consist principally of receipts in respect of goods or services provided in the course of both the existing operations financed by means of the Fund and the additional operations financed by means of the Fund by virtue of this Order.

It also appears to the Secretary of State that the financing of the operations in question by means of the Fund would be in the interests of the improved efficiency and effectiveness of the management of those operations.

In accordance with section 2(1)(a) of the 1973 Act(**3**), the Secretary of State has determined with Treasury concurrence that no Crown assets or liabilities, other than those already appropriated to the Fund, are properly attributable to any additional operations financed by means of the Fund by virtue of this Order.

In accordance with section 4A(2) of the 1973 Act(**4**), the Secretary of State has determined with Treasury concurrence that no assets or liabilities of the Fund are properly attributable to any operations ceasing to be financed by means of the Fund by virtue of this Order.

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.

(**1**) 1973 c.63. Section 1 was substituted, except in relation to Crown Suppliers, by section 1(1) of the Government Trading Act 1990 (c.30) (the 1990 Act); section 6(1) was substituted, except in relation to Crown Suppliers, by section 2(3) of the 1990 Act. *See* section 1(7) for the definition of "Minister of the Crown". *See also* section 1(2), which provides that a power to make an order under section 1 is only exercisable with Treasury concurrence.
(**2**) S.I. 2003/1076; this instrument has been amended by S.I. 2005/2061, 2006/2407, 2011/1043, 2012/1916 and 2014/432.
(**3**) Section 2 was substituted by section 1 of the 1990 Act and amended by the Finance Act 1991 (c.31), section 119(3), and the Finance Act 1993 (c.34), Schedule 22, paragraph 2.
(**4**) Section 4A was inserted by section 1(2) of the Government Trading Act 1990 (c.30) (the 1990 Act).
(**5**) Section 6(2) was substituted by section 2(3) of the 1990 Act.

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) (EU Exit) Order 2018 and comes into force on the day after the day on which it is made.

(2) In this Order, "the MHRA Trading Fund Order" means the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**6**).

Amendment of article 1 of the MHRA Trading Fund Order

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

(a) in paragraph (2), omit the definition of "tissue bank" and the "and" preceding it; and

(b) for paragraph (4), substitute—

"(4) In this Order "electronic cigarette" and "refill container" have the meanings given to them by regulation 2(1) of the Tobacco and Related Products Regulations 2016(**7**).".

Substitution of Schedule 1 to the MHRA Trading Fund Order

3. For Schedule 1 to the MHRA Trading Fund Order (funded operations), substitute—

"SCHEDULE 1 Article 2

FUNDED OPERATIONS

1. All the operations of that part of the Department of Health and Social Care known from 1st April 2003 as the Medicines and Healthcare Products Regulatory Agency (the Agency) carried out in connection with the following—

(a) the regulation of medicinal products;

(b) the regulation of clinical trials of medicinal products;

(c) the characterisation, standardisation and control of biological medicinal products;

(d) the regulation of medical devices;

(e) the regulation of products or devices that are similar to medicinal products or medical devices where this is ancillary to the regulation of medicinal products or medical devices;

(f) the regulation of collecting, testing, processing, storage and distribution of human blood and human blood components;

(g) the application of the principles of good laboratory practice;

(h) the regulation of electronic cigarettes and refill containers;

(i) the provision of services (including online services) relating to public health or the matters mentioned at sub-paragraphs (a) to (h).

2. Any operations of the Agency carried on in connection with any proposed legislation relating to the matters mentioned at paragraph 1(a) to (i), including legislative proposals being prepared in connection with the withdrawal of the United Kingdom from the European Union.

(**6**) S.I. 2003/1076; this instrument has been amended by S.I. 2004/994, 2005/2061, 2006/2407, 2011/1043, 2012/1916, 2014/432, 2016/549 and 2018/378.

(**7**) S.I. 2016/507, to which there are amendments not relevant to this Order.

3. Any operations of the Agency carried on in connection with the dissemination of information relating to the matters mentioned at paragraph 1(a) to (i).

4. Any operations of the Agency which are incidental, conducive or are otherwise ancillary to the operations described in paragraphs 1 to 3.

5. In this Schedule—

"regulation" does not include—

(a) the regulation of prices;

(b) the regulation of the availability of products as part of the health service; or

(c) in relation to medical devices or devices similar to medical devices, the provision of device evaluation services;

"provision of services" includes (but is not limited to)—

(a) assistance to other regulatory authorities, other Government departments or agencies or public bodies;

(b) advisory, information, education or training services;

(c) the collection, processing, analysis or provision of data and enabling clinical studies based on that data;

(d) the sale of reference substances;

(e) the sale of publications."

Signed by authority of the Secretary of State.

O'Shaughnessy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

18th October 2018

We concur

Rebecca Harris
Paul Maynard
Two of the Lords Commissioners of Her Majesty's Treasury

23rd October 2018

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (the Trading Fund Order) in order to remove references to European Union legislation that would no longer be appropriate after the withdrawal of the United Kingdom from the European Union. This Order re-states the operations covered by the Trading Fund Order in a more transparent way but without changing the broad substance of the operations covered.

A full impact assessment has not been prepared for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.