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

DRAFT STATUTORY INSTRUMENTS

2016 No. 0000

GOVERNMENT TRADING FUNDS

The Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) Order 2016

Made - - - -	***
Coming into force - -	***

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

It appears to the Secretary of State that the operations of the Department of Health covered by this Order (the additional operations) are suitable to be financed by means of the fund established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003(**b**) (the Fund) and, in particular, to be 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 and services provided in the course of those operations.

It also appears to the Secretary of State that the financing of the additional operations 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 of the 1973 Act(**c**), 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 the additional operations.

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

(**a**) 1973 c.63. Section 1 was substituted by section 1(1) of the Government Trading Act 1990 (c.30) (the 1990 Act); section 6 was substituted by section 2(3) of the 1990 Act. *See* section 1(7) for the definition of "Minister of the Crown".
(**b**) S.I. 2003/1076; this instrument has been amended by S.I. 2005/2061, 2006/2407, 2011/1043, 2012/1916 and 2014/432.
(**c**) Section 2 was substituted by section 1 of the 1990 Act.
(**d**) 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) Order 2016 and shall come into force on the day after it is made.

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

Amendment of article 1 of the MHRA Trading Fund Order

2. After article 1(3) of the MHRA Trading Fund Order(**a**) (interpretation) insert—

"(4) In this Order "electronic cigarettes" and "refill containers" have the meaning given to them by article 2 of Directive 2014/40/EU of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products(**b**).".

Amendment of Schedule 1 to the MHRA Trading Fund Order

3.—(1) Schedule 1 to the MHRA Trading Fund Order(**c**) (funded operations) is amended as follows.

(2) After paragraph 1(c) insert—

"(cc) the functions of the United Kingdom and its national competent authority under Article 20 of Directive 2014/40/EU of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (electronic cigarettes) and related implementing legislation;".

(3) In paragraph 1(e) after "or devices" insert "or electronic cigarettes and refill containers".

(4) In paragraph 1(f) after "device evaluation services," insert "or electronic cigarettes and refill containers".

Signed by authority of the Secretary of State.

Name
Minister of State
Department of Health

Date

We concur

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

Date

(**a**) Article 1 has been amended by S.I. 2005/2061 and 2012/1916.
(**b**) OJ L 127, 29.4.2014, p.1 as amended by Commission Delegated Directive 2014/109/EU, OJ L 360, 17.12.2014.
(**c**) Schedule 1 has been amended by S.I. 2005/2061, 2006/2407 and 2011/1043.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines and Healthcare Product Regulatory Agency Trading Fund Order 2003 in order to add functions relating to the regulation of electronic cigarettes and associated refill containers to the list of operations funded through the trading fund.

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

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