EXPLANATORY MEMORANDUM TO

THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY TRADING FUND (AMENDMENT) (EU EXIT) ORDER 2018

2018 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care and is laid before the House of Commons by Command of Her Majesty.

1.2 This memorandum contains information for the Select Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This Order amends the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003. It does so in order to remove references to obligations under European Union (EU) legislation. These references will no longer be appropriate once the UK withdraws from the EU. It also re-states the activities covered by Trading Fund in a more transparent way. The amendments are made under a power in the Government Trading Funds Act 1973 (the 1973 Act) which allows expressly for the amendment of Trading Fund Orders.

3. Matters of special interest to Parliament

Matters of special interest to the Select Committee on Statutory Instruments

3.1 The intention is to bring this affirmative instrument into force on the day after it is made. The JCSI has previously criticised an affirmative instrument which came into force on the day after making (see JCSI's 1st Report of Session 2013-14). However, we believe the criticism does not apply here because the JCSI noted that the offending instrument "significantly diminishes the legal rights of persons affected, or imposes new duties on such persons which are significantly more onerous then before, and requires them to adopt different patterns of behaviour accordingly"; by contrast, this instrument makes technical accounting changes and has no direct impact on third parties. The policy reasons behind the choice of coming into force date are set out at paragraph 7.9.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

4. Extent and Territorial Application

4.1 This instrument extends to all of the United Kingdom.

4.2 This instrument applies to all of the United Kingdom.

5. European Convention on Human Rights

5.1 Lord O'Shaughnessy has made the following statement regarding Human Rights:

"In my view the provisions of the Medicines and Healthcare Products Regulatory Agency Trading Fund (Amendment) (EU Exit) Order 2018 are compatible with the Convention rights."

6. Legislative Context

6.1 Trading funds were introduced by the 1973 Act as a means of financing the revenue-generating operations of a Government department which up until then had been financed through the Supply-process. The 1973 Act does not define "trading fund", but a Government White Paper titled The Financing and Accountability of Next Steps Agencies (December 1989) describes it as a "financing framework which covers operating costs and receipts, capital expenditure, borrowing and net cash flow" (Cm 914). The White Paper preceded the revisions made to the 1973 Act by the Government Trading Act 1990.

6.2 A trading fund operates outside the Supply-process and has standing authority to meet all outgoings from receipts. Being outside the Supply process means that no detailed advance approval by Parliament of its income and expenditure is required. The operations financed by a trading fund must be managed so that the revenue of the fund is sufficient to meet its expenditure on those operations.

6.3 The MHRA is financed by a trading fund established by the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003 (the MHRA Trading Fund Order), which was made under the 1973 Act.

6.4 The operations that fall within the MHRA's trading fund are set out in Schedule 1 to the MHRA Trading Fund Order. These are the operations that the MHRA can fund using the revenue it generates from those operations. These are referred to as the "funded operations".

6.5 The MHRA's funded operations - as set out in Schedule 1 - are, in places, identified by cross-references to functions arising under specified pieces of EU legislation. The primary purpose of this instrument is to remove the cross-references to EU legislation from Schedule 1 prior to the United Kingdom's withdrawal from the EU in order that the MHRA's trading fund will remain fully operational after that time.

6.6 This instrument is subject to affirmative procedure. This is in accordance with section 6(2) of the 1973 Act which provides that instruments that extend or restrict the funded operations of a trading fund must be laid before, and approved by a resolution of, the House of Commons (only) prior to being made. This instrument re-states the funded operations in a clearer and more transparent way. The adoption of different, higher level descriptors for the funded operation inevitably introduces marginal changes to the scope of the funded operations. For this reason, the affirmative resolution procedure is the correct Parliamentary procedure for this instrument because that procedure applies where the funded operations have been extended or restricted.

6.7 This instrument has not been published in draft before being laid.

7. Policy background

What is being done and why?

7.1 This is an EU Exit SI made under existing powers (sections 1 and 6 of the 1973 Act).

What did the relevant EU law do before exit day?

7.2 The MHRA Trading Fund Order establishes the MHRA as a trading fund and sets out the terms under which that trading fund operates (see section 4 on legislative background for further details). The MHRA Trading Fund Order is not generally considered to be EU law because the establishment and terms of a Government trading fund is a purely national matter. However, Schedule 1 does contain multiple cross-references to specific pieces of EU legislation as a way of identifying functions financed by the trading fund.

Why are you changing it?

7.3 The cross-references to EU legislation in Schedule 1 will no longer achieve the intended purpose of identifying the MHRA's funded operations when the United Kingdom withdraws from the EU insofar as the United Kingdom is no longer bound by EU legislation and functions do not arise from that legislation. The purpose of this instrument is to 'fix' these cross-references to EU legislation.

7.4 Although we are also taking this opportunity to re-state Schedule 1 in clearer terms, that re-statement is not the reason for this instrument – we would not have proceeded with a re-statement in isolation. However, having determined that an instrument was need to 'fix' the references to EU legislation we considered it sensible to improve the readability of Schedule 1 at the same time.

What will it now do?

7.5 This instrument amends the MHRA Trading Funder Order in order to remove the cross-references to EU legislation from Schedule 1 and re-casts Schedule 1 so that the MHRA's funded operations are identified by subject area and not by reference to the legislation underpinning the subject area. This approach of identifying the funded operations by subject area rather than specific pieces of legislation is a common approach taken in many other Trading Fund Orders[1]. Amongst other reasons, this approach ensures that the trading fund is not automatically extended where underpinning legislation is amended to add functions in new areas, thus bypassing Parliamentary scrutiny of an extension to a trading fund.

7.6 Although it is not the MHRA's intention to alter the scope of the operations that it can carry out under its trading fund, it is acknowledged that any re-casting of provisions can bring about changes to the scope of those provisions. By re-stating the provisions at the level of subject area it is accepted that this may be the case here despite steps having been taken to restrict the subject area descriptions where appropriate: see paragraph 5 of the substituted Schedule 1 and the limited interpretation of "regulation". However, the MHRA is not looking to carry out any new activity on the basis of these changes to its trading fund; nor is the trading fund being amended to enable the MHRA to introduce new fees that it would not otherwise be able to

[1] For example see the Patent Office Trading Fund Order (1991/1796), the Defence, Science & Technology Trading Fund Order (S.I.2011/148; revoked in 2017) and the Foreign and Commonwealth Office Services Trading Fund Order (S.I. 2008/590).

introduce. The MHRA's intention is only to remove the references to EU legislation and - as part of the necessary re-working of the Order - to modernise Schedule 1 so as to make it clearer to read and more transparent in its terms.

7.7 This instrument will enable the MHRA to remain fully functioning as a trading fund following the United Kingdom's withdrawal from the EU irrespective of the future relationship between United Kingdom and the EU. The manner in which Schedule 1 has been re-cast (i.e. without reference to the underpinning legislation) also has the benefit that the MHRA's trading fund would remain fully functioning during any implementation period agreed between the United Kingdom and the EU.

7.8 Additionally, this instrument introduces into Schedule 1 express reference to four activities. In each case, the activity already falls within the funded operations but the significance of these four particular activities would seem to merit their express mention as funded operations. They are:

(i) the regulation of clinical trials of medicinal products for human use: see paragraph 1(b) of substituted Schedule 1. The MHRA has been carrying out this work since its inception in 2003 and although this is part of the wider regulation of medicinal products for human use it is an important aspect in it is own right.

(ii) work in relation to the characterisation, standardisation and control of biological medicinal products: see paragraph 1(f) of substituted Schedule 1. The MHRA has been carrying out this important work through the National Institute for Biological Standards and Control (NIBSC) since NIBSC - a global leader in relation to biological medicines - became part of the wider MHRA in 2013.

(iii) work on preparing legislation, including on a contingency basis, in connection with the United Kingdom's withdrawal from the EU: see paragraph 2 of substituted Schedule 1 which now mentions expressly the legislative proposals being prepared in connection with the United Kingdom's withdrawal. This is work that is being done in advance of exit day. Although this work is already covered by Schedule 1, the MHRA were keen - given the importance of the work being done on a contingency basis – that this work was expressly acknowledged in Schedule 1. This is not something we would have done had we not been amending Schedule 1 in any event; but as we were an express reference has been included as part of the re-statement.

(iv) work done to enable clinical studies to be carried out using data provided to third parties by the MHRA: see paragraphs 1(h) and 5(c) of substituted Schedule 1 which adds words to this effect. The MHRA has been carrying out this work through Clinical Practice Research Datalink (CPRD) since CPRD was created in 2012.Finally, this instrument removes from Schedule 1 the following example of a service that falls within the funded operations: "the inspection or accreditation of tissue banks". This example is removed because it relates to an activity that the MHRA no longer undertakes and so its express inclusion as an example of a service that may be provided is unhelpful

Timing of the instrument

7.9 This instrument will need to come into force on or before exit day in order that the references to EU legislation are removed in advance of the United Kingdom's withdrawal from the EU. However, the way the new Schedule 1 has been drafted means that it will operate effectively irrespective of the United Kingdom's relationship with the EU and for this reason this instrument is able to come into force

before exit day. Given that the new Schedule 1 (i) introduces a reference to work taking place pre-exit (see paragraph 7.8(iii)); (ii) is, in our view, clearer and therefore an improvement; and (iii) works in all pre-exit and post-exit scenarios, we see no reason to delay any further than necessary the coming into force of this instrument. For this reason, this instrument is scheduled to come into force on the day after it is made.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is not being made under the European Union (Withdrawal) Act 2018 but relates to the withdrawal of the United Kingdom from the EU because it removes references to EU legislation in the MHRA's Trading Fund Order which will cease to be operable as a result of the United Kingdom's withdrawal from the EU (see further paragraphs 6.5 and 7.2-3).

9. Consolidation

9.1 There are no plans to consolidate the MHRA Trading Fund Order at this time.

10. Consultation outcome

10.1 No consultation has been undertaken. The Minister did not consider that it was appropriate to consult on this technical accounting change which, for the main part, only re-casts the MHRA Trading Fund Order in order to remove references to EU legislation.

11. Guidance

11.1 Not applicable. The changes do not have any implications outside the MHRA.

12. Impact

12.1 There is no impact on business, charities or voluntary bodies.

12.2 There is no impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the proposed amendments do not involve any substantive changes to currently funded operations nor do they have any negative financial implications.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The terms of the MHRA Trading Fund Order are reviewed whenever new functions are conferred on the MHRA.

15. Contact

15.1 Anne Ryan at the MHRA Telephone: 0203 080 6392 or email: anne.ryan@mhra.gov.uk can answer any queries regarding the instrument.

15.2 Patience Wilson at the MHRA can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord O'Shaughnessy at the Department of Health can confirm that this Explanatory Memorandum meets the required standard.