Draft Regulations laid before Parliament under paragraphs 8F(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2021 No. 0000

EXITING THE EUROPEAN UNION
MEDICINES

The Human Medicines (Amendment etc.) (EU Exit) (No. 2) Regulations 2021

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

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8C of, and paragraphs 1(1)(ab) and 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**).

The Treasury has consented to the making of these Regulations as required by paragraphs 3(1) and 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

In accordance with paragraphs 8F(1) and 12(1) of Schedule 7 to the European Union (Withdrawal) Act 2018(**2**), a draft of these Regulations has been laid before, and approved by, a resolution of each House of Parliament.

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Human Medicines (Amendment etc.) (EU Exit) (No. 2) Regulations 2021 and come into force on the day after the day on which they are made.

(**1**) 2018 c. 16. Section 8C was inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 (c. 1), paragraph 1(1)(ab) of Schedule 4 was inserted by section 28 of that Act, and paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to that Act.

(**2**) Paragraph 8F of Schedule 7 was inserted by paragraph 51 of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 (c. 1).

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**3**) are amended in accordance with Part 2.

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

3. The Medicines (Products for Human Use) (Fees) Regulations 2016(**4**) are amended in accordance with Part 3.

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

4. The Medicines for Human Use (Clinical Trials) Regulations 2004(**5**) are amended in accordance with Part 4.

PART 2

Amendment of the Human Medicines Regulations 2012

Amendment of regulation 8 (general interpretation)

5. In regulation 8(1)(**6**), in the definition of "homoeopathic medicinal product", in paragraph (b)(i), for "in an pharmacopoeia used officially in an country" substitute "in a pharmacopoeia used officially in a country".

Amendment of regulation 43 (obligations of licence holder)

6. In regulation 43(6)(d)(**7**)—

(a) at the end of sub-paragraph (i), omit "or";

(b) in sub-paragraph (ii), for "import." substitute "import; or"; and

(c) at the end insert—

"(iii) from the United Kingdom to a person in an EEA State, if the distribution is specifically for purposes of placing the product on the market in that State and the medicinal product has—

(aa) a marketing authorisation,

(bb) Article 126a authorisation,

(cc) certificate of registration, or

(dd) traditional herbal registration for that EEA State."

Amendment of regulation 45A (brokering in medicinal products)

7. In regulation 45A(1A)(**8**)—

(a) in sub-paragraph (b)(i), omit "or a competent authority of a member State"; and

(**3**) S.I. 2012/1916.
(**4**) S.I. 2016/190.
(**5**) S.I. 2004/1031.
(**6**) Regulation 8 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488); there are other amending instruments but none is relevant.
(**7**) Regulation 43(6) was amended by S.I. 2016/186 and 2019/775 (as amended by S.I. 2020/1488).
(**8**) Regulation 45A was inserted by S.I. 2013/1855 and amended by S.I. 2019/775 (as amended by S.I. 2020/1488).

(b) in sub-paragraph (b)(ii), omit "except where the person is validly registered with the competent authority of an EEA state,".

Amendment of regulation 49 (application for grant of UK marketing authorisation or parallel import licence)

8.—(1) Regulation 49(**9**) is amended as follows.

(2) For paragraph (3)(a) substitute—

"(a) a UKMA(UK) or UKMA(NI), must be established in the United Kingdom or the European Union;".

(3) In paragraph (3)(b)(ii), after "the United Kingdom" insert "or the European Union".

(4) In paragraph (3)(c), for "UKMA(UK)" substitute "parallel import licence".

Amendment of regulation 58 (consideration of application)

9. In regulation 58(**10**), after paragraph (4C) insert—

"(4D) When considering an application for a UK marketing authorisation, the licensing authority may, if it considers appropriate, grant a UKMA(UK), UKMA(GB) or UKMA(NI), regardless of the indication given under regulation 49(9)."

Amendment of regulation 60A (condition as to the submitting of samples and other information to the appropriate authority)

10.—(1) Regulation 60A(**11**) is amended as follows.

(2) In paragraph (1), in the definition of "the batch testing exemption", in paragraph (b)(ii), after "United Kingdom" insert "or, in the case of a product for sale or supply in Northern Ireland, the European Union".

(3) In paragraph (2), in each place where it occurs, for "immunological product" substitute "immunological medicinal product".

Amendment of regulation 60B (submitting of samples and other information: EU marketing authorisations)

11.—(1) Regulation 60B(**12**) is amended as follows.

(2) In paragraph (1), in the definition of "the batch testing exemption", in paragraph (b)(ii), after "United Kingdom" insert "or the European Union"

(3) In paragraph (2)(a), in each place where it occurs, for "immunological product" substitute "immunological medicinal product".

Amendment of regulation 167 (supply to fulfil special patient needs)

12. In regulation 167(7)(**13**), omit "a country other than".

(**9**) Regulation 49(3) was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**10**) Regulation 58 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**11**) Regulation 60A was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**12**) Regulation 60B was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**13**) Regulation 167(7) was amended by S.I. 2017/715 and 2019/775 (as amended by S.I. 2020/1488).

Amendment of regulation 182 (obligation on holder to operate pharmacovigilance system)

13. In regulation 182(2)(a)(**14**), for "the EU or" substitute "an EEA State or the".

Amendment of regulation 188 (reporting obligations on holders)

14.—(1) Regulation 188(**15**) is amended as follows.

(2) In paragraph (1A)(a), after "15 days beginning on the day" insert "following the day".

(3) In paragraph (1A)(b), after "90 days beginning on the day" insert "following the day".

Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)

15.—(1) Regulation 193(**16**) is amended as follows.

(2) In paragraph (6A), for "paragraph (2)(a)" substitute "paragraph (2A)(a)".

(3) In paragraph (6B), for "paragraph (2)" substitute "paragraph (2A)".

Amendment of regulation 199 (submission of draft study protocols for required studies)

16.—(1) Regulation 199(**17**) is amended as follows.

(2) For paragraph (2)(a), substitute—

"(a) the licensing authority; and".

(3) For paragraph (2)(b), substitute—

"(b) where the authorisation is a UKMA(NI) or UKMA(UK) and the study is to be conducted in an EEA State, the Pharmacovigilance Risk Assessment Committee,".

(4) Omit paragraph (3).

(5) In paragraph (4), for "paragraphs (2) and 3(a)" substitute "paragraph (2)(a)".

Amendment of regulation 200 (amendment to study protocols for required studies)

17.—(1) Regulation 200(**18**) is amended as follows.

(2) For paragraph (2)(a), substitute—

"(a) the licensing authority; and"

(3) For paragraph (2)(b), substitute—

"(b) where the authorisation is a UKMA(NI) or UKMA(UK) and the study is being conducted in an EEA State, the Pharmacovigilance Risk Assessment Committee,"

(4) Omit paragraph (3).

(5) In paragraph (4), for "paragraphs (2) and (3)(a)" substitute "paragraph (2)(a)".

(6) In paragraph (6), for "paragraphs (2) and (3)(b)" substitute "paragraph (2)(b)".

Amendment of regulation 201 (submission and evaluation of final study reports for required studies)

18.—(1) Regulation 201(**19**) is amended as follows.

(**14**) Regulation 182(2) was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**15**) Regulation 188(1A) was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**16**) Regulation 193 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**17**) Regulation 199 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**18**) Regulation 200 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**19**) Regulation 201 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).

(2) For paragraph (2)(a), substitute—

"(a) the licensing authority; and"

(3) For paragraph (2)(b), substitute—

"(b) where the authorisation is a UKMA(NI) or UKMA(UK) and the study was conducted in an EEA State, the Pharmacovigilance Risk Assessment Committee,"

(4) Omit paragraph (3).

Amendment of regulation 202A (licensing authority power in relation to medicinal products subject to additional monitoring)

19. For regulation 202A(1)(**20**) substitute—

"(1) The licensing authority may establish a list of medicinal products that are subject to additional monitoring and that are authorised under—

(a) a UKMA(GB), and

(b) a UKMA(UK) where the medicinal product is not on the list referred to in Article 23 of Regulation (EC) No 726/2004."

Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)

20.—(1) Schedule 8(**21**) is amended as follows.

(2) In paragraph 12, in the two places where it occurs, for "a member State" substitute "an EEA State".

(3) For paragraph 23 substitute—

"**23.** For medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004 or regulation 202A, as the case may be, the symbol and statement "▼ This medicinal product is subject to additional monitoring". "

Amendment of Schedule 11 (advice and representations)

21. In Schedule 11(**22**), in paragraph 1(2) (application of this part), after "UKMA(NI)" insert ", COR(NI)".

Amendment of Schedule 27 (package leaflets)

22. In Schedule 27(**23**), in paragraph 13, for "in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation in the case of products for sale or supply in Great Britain" substitute "or regulation 202A, as the case may be,".

Amendment of Schedule 33A (transitional provisions)

23. In Schedule 33A(**24**), omit Part 10 (transitional provisions in respect of pharmacovigilance).

(**20**) Regulation 202A was inserted by S.I. 2019/775.
(**21**) Schedule 8 was amended by S.I. 2013/1855 and 2019/775 (as amended by S.I. 2020/1488).
(**22**) Schedule 11 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**23**) Schedule 27 was amended by S.I. 2014/1878 and 2019/775 (as amended by S.I. 2020/1488).
(**24**) Schedule 33A was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).

PART 3

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

Amendment of regulation 19F (fee for testing of samples by the appropriate authority)

24.—(1) Regulation 19F(**25**) is amended as follows.

(2) In paragraph (1), after "regulation 60A" insert "or a batch testing requirement imposed under regulation 60B".

(3) In paragraph (3)—

(a) for ""appropriate authority" and "batch testing condition"" substitute ""appropriate authority", "batch testing condition" and "batch testing requirement""; and

(b) after "regulation 60A" insert "or 60B (as appropriate)".

Amendment of regulation 27A (fee for renewals of a marketing authorisation)

25. In regulation 27A(**26**), after "in the case of a product for sale or supply in Great Britain" insert ", except where the marketing authorisation was granted under Chapter 4 of Title III of the 2001 Directive,".

Amendment of regulation 46 (fees for applications for certificates)

26. Omit regulation 46(2).

Amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates)

27. In Schedule 2(**27**), in paragraph 56—

(a) in sub-paragraph (a), after "unfettered access route," insert "provided a corresponding renewal has been made to the related European Union marketing authorisation or UKMA(NI) for the same product,";

(b) in sub-paragraph (b), after "(an automatic recognition application)," insert "provided a corresponding renewal has been made to the related European Union marketing authorisation or UKMA(NI) for the same product,";

(c) for sub-paragraph (c), substitute—

"(c) in respect of an application for renewal of a UKMA(UK) or a UKMA(GB) granted under an application other than under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive, provided a corresponding renewal has been made to the related marketing authorisation or UKMA(NI) for the same product, £747;";

(d) at the end insert—

"(d) in all other cases, £9,682.".

Amendment of Schedule 5 (fees for certificates of registration)

28. For the table in Schedule 5, substitute—

(**25**) Regulation 19F was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**26**) Regulation 27A was inserted by S.I. 2019/775 (as amended by S.I. 2020/1488).
(**27**) Schedule 2 was amended by S.I. 2019/775 (as amended by S.I. 2020/1488).

"Column 1		*Column 2*	*Column 3*
	Type of application	*Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	*Fees for other applications*
1	An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation.	£159	£393
2	An application in respect of a product which is either— (a) Prepared solely from repeat stocks; or (b) Is of a repeat formulation.	£478	£704
3	A mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associate application under the unfettered access route for a COR(GB).	£501	£638
4	A decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a COR(GB).	£430	£563
5	Any other application.	£790	£1,034".

PART 4

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

Amendment of regulation 57 (functions in relation to good clinical practice)

29. In regulation 57(1)(**28**) omit ", in respect of Great Britain".

Signed by authority of the Secretary of State for Health and Social Care

Name
Minister of State
Date
Department of Health and Social Care

(**28**) Regulation 57 was inserted by S.I. 2019/744 (as amended by S.I. 2020/1488).

We consent

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

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8C of the European Union (Withdrawal) Act 2018 (c. 16) in order to deal with matters arising out of, or related to, the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement. They are also made under paragraphs 1(1)(ab) and 7(2) of Schedule 4 to the European Union (Withdrawal) Act 2018 (insofar as they make provision in relation to fees) and paragraph 21 of Schedule 7 (in relation to transitional arrangements).

These Regulations make amendments to legislation in the field of the regulation of medicinal products for human use. These are minor and technical amendments to ensure that the instruments governing medicines, clinical trials and fees associated with the regulation of medicines continue to be effective in Northern Ireland and Great Britain, taking into account the Northern Ireland Protocol.

Part 2 amends the Human Medicines Regulations 2012 (S.I. 2012/1916). Part 3 amends the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190). Part 4 amends the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031). The amendments made by these Regulations relate to the manufacture and distribution of medicinal products and active substances, marketing authorisations, pharmacovigilance, fees and functions in relation to good clinical practice.

An impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument at www.legislation.gov.uk.