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).