This Statutory Instrument has been printed to correct an error in S.I. 2020/1488 (which amended S.I. 2019/775, which amended S.I. 2012/1916) and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2021 No. 834

EXITING THE EUROPEAN UNION
MEDICINES

The Human Medicines (Amendment) (EU Exit) Regulations 2021

Made - - - -	*12th July 2021*
Laid before Parliament	*13th July 2021*
Coming into force - -	*3rd August 2021*

The Secretary of State for Health and Social Care makes these Regulations in exercise of the powers conferred by section 8C(1) of the European Union (Withdrawal) Act 2018(**1**).

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) (EU Exit) Regulations 2021.

(2) These Regulations come into force on the twenty-first day after the day on which they are laid before Parliament.

(3) These Regulations extend to the whole of the United Kingdom.

Amendment of regulation 3 of the Human Medicines Regulations 2012

2. In regulation 3 of the Human Medicines Regulations 2012 (scope of these Regulations: special provisions), in paragraph (15), after sub-paragraph (a) insert—

"(aa) an EU marketing authorisation;".

(**1**) 2018 c. 16; section 8C was inserted by the European Union (Withdrawal Agreement) Act 2020 (c. 1), section 21.

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

3. In regulation 5 of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019(**2**) (amendment of regulation 3 (scope of Regulations: special provisions)), in paragraph (3), omit sub-paragraph (b).

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020

4. In Schedule 2 to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020(**3**) (amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019), in paragraph 2, omit sub-paragraph (b).

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

Edward Argar
Minister of State,
Department of Health and Social Care

12th July 2021

(**2**) S.I. 2019/775; the relevant amending instrument is S.I. 2020/1488.
(**3**) S.I. 2020/1488.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the HMRs"), which govern the arrangements throughout the United Kingdom for the manufacture, importation and marketing of medicinal products for human use. Regulation 3 of the HMRs contains exemptions from the manufacturing and product licensing requirements of the HMRs that relate to the manufacture or assembly of medicines by doctors, dentists, nurses and midwives at the final stage of the medicines supply chain – and related to those exemptions, there are provisions of regulation 3 that deal with the packaging, labelling and leafleting requirements for the products covered by those exemptions.

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 ("the 2019 Regulations") made an amendment to an interpretation provision in paragraph (15) of regulation 3 that related to the repackaging, labelling and leafleting requirements in the case of products covered by a specified list of types of authorisations. Regrettably, because of a numbering error in the drafting of the amendment, introduced into the 2019 Regulations by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, the attempt to add "EU marketing authorisation" to the list of types of authorisations was ineffective. These Regulations correct that numbering error and restore the original drafting intention.

Consequential amendments are made to the provisions that contained the numbering error.