STATUTORY INSTRUMENTS

2023 No. 437

MEDICINES

The Human Medicines (Amendment) Regulations 2023

Made - - - -	*18th April 2023*
Laid before Parliament	*19th April 2023*
Coming into force - -	*17th May 2023*

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) Regulations 2023 and come into force on the twenty-eighth day after the day on which they are laid before Parliament.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendment of the Human Medicines Regulations 2012

2. The Human Medicines Regulations 2012(**2**) are amended in accordance with regulations 3 to 5.

Amendment of regulation 17 (manufacturing of medicinal products)

3.—(1) Regulation 17(**3**) is amended as follows.

(2) In paragraph (2), for "paragraphs (3) to (5)" substitute "paragraphs (3) to (9)".

(3) After paragraph (8) insert—

"(9) Paragraph (1)(d) does not apply to the importation of a medicinal product into Northern Ireland from Great Britain by the holder of a wholesale dealer's licence, where the following conditions are met—

(a) the medicinal product has undergone—

(i) in an EEA State, the quality control testing provided for by Article 51 of the 2001 Directive, or

(**1**) 2018 c. 16. Section 8C was inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 (2020 c.1) ("the 2020 Act") and amended by section 55(3) of the United Kingdom Internal Market Act 2020 (c.27). Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act.

(**2**) S.I. 2012/1916.

(**3**) Regulation 17 was amended by S.I. 2019/775, as amended by S.I. 2020/1488.

(ii) in the United Kingdom, checks in accordance with these Regulations and the requirements of the marketing authorisation relating to the product and that these are appropriately certified;

(b) the batch release of the medicinal product has been undertaken—

(i) in Northern Ireland or an EEA State, by a qualified person in accordance with Article 51(1) of the 2001 Directive, and it is accompanied by the appropriate control reports, or

(ii) in Great Britain, by a qualified person applying equivalent standards;

(c) the medicinal product has a UKMA(UK) or UKMA(NI);

(d) the importation of the medicinal product is with a view to its sale or supply in Northern Ireland only; and

(e) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive, that the features specified in paragraph 18A of Schedule 24 are affixed on the packaging.".

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

4. In regulation 49(3)(**4**)—

(a) for sub-paragraph (a) substitute—

"(a) a UKMA(UK) or UKMA(NI), must be established in the United Kingdom or an EEA State;";

(b) in sub-paragraph (b)(ii), after "the United Kingdom" insert "or an EEA State"; and

(c) in sub-paragraph (c), for "UKMA(UK)" substitute "parallel import licence".

Insertion of new regulation 345A (obligation on licensing authority to maintain list of medicinal products to which derogations have applied)

5. After regulation 345 insert—

"**Obligation on licensing authority to maintain list of medicinal products to which derogations have applied**

345A.—(1) The licensing authority must publish a list of medicinal products to which the derogations described in Articles 5a, 8(2a) and (2b), 18a, 20 (second paragraph), 40(1a) and (3a), 48(3) and 104(3) of the 2001 Directive have applied.

(2) The licensing authority must update the list referred to in paragraph (1) at least every six months.".

(**4**) Regulation 49(3) was substituted by S.I. 2019/775, as amended by S.I. 2020/1488.

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

Maria Caulfield
Parliamentary Under-Secretary of State,
Department of Health and Social Care

18th April 2023

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to legislation in the field of the regulation of medicinal products for human use. These amendments ensure that the Human Medicines Regulations 2012 (S.I. 2012/1916, "the 2012 Regulations") continue to be effective in Northern Ireland and Great Britain, taking into account the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community. They transpose provisions from Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (OJ No. L 118, 20.4.2022, p.4). The transposition note is published alongside the instrument at legislation.gov.uk .

Regulation 3 amends regulation 17 of the 2012 Regulations to provide an exemption from the requirement to hold a manufacturer's licence when the holder of a wholesale dealer's licence imports medicinal products into Northern Ireland from Great Britain in specified circumstances.

Regulation 4 amends regulation 49 of the 2012 Regulations to permit the holder of a marketing authorisation for a medicinal product that applies in the whole of the UK, or Northern Ireland only, to be established in the United Kingdom or an EEA State. It also makes the rules on establishment consistent in the case of holders of GB-only marketing authorisations and parallel import licences.

Regulation 5 inserts a new regulation into the 2012 Regulations, which requires the licensing authority for human medicines in the UK to maintain and keep up to date a list of medicinal products that have benefited from certain derogations in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.