
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

[^{F1}Application for UKMA(NI) relating to generic medicinal products

51.—(1) An applicant for a UKMA(NI) for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UKMA(NI) for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in Northern Ireland before the time at which it may be placed on the market in accordance with Article 10(1) of the 2001 Directive as modified by paragraph (3).

(3) The second subparagraph of Article 10(1) of the 2001 Directive has effect with the exception described in paragraph (4).

(4) Where—

- (a) ten years have elapsed since a UK marketing authorisation was granted otherwise than under Chapter 4 of Title III to the 2001 Directive in relation to the reference medicinal product;
- (b) in relation to that product there is—
 - (i) an EU marketing authorisation, or
 - (ii) a UKMA(NI) which was granted under that Chapter; and
- (c) a period of ten years has not elapsed since the authorisation mentioned in sub-paragraph (b) for sale or supply of that product in the European Union,

the product may not be made available for sale or supply in Northern Ireland until the period mentioned in sub-paragraph (c) has elapsed.]

Textual Amendments

F1 Regs. 51-51B substituted for reg. 51 (31.12.2020) by S.I. 2019/775, regs. 1, 56 (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, Sch. 2 para. 41)

Changes to legislation:

The Human Medicines Regulations 2012, Section 51 is up to date with all changes known to be in force on or before 05 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- reg. 51 substituted by [S.I. 2019/775 reg. 56](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 56 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 41)
- reg. 51(2) words omitted by [S.I. 2024/832 reg. 34\(a\)](#)
- reg. 51(3) omitted by [S.I. 2024/832 reg. 34\(b\)](#)
- reg. 51(4) omitted by [S.I. 2024/832 reg. 34\(b\)](#)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by [S.I. 2019/775 reg. 63\(2\)\(a\)\(ii\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by [S.I. 2024/832 reg. 142\(e\)](#)
- Sch. 24 Pt. 1 para. 23 words omitted by [S.I. 2024/832 reg. 142\(f\)](#)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(4\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(3\)\(b\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by [S.I. 2019/1385 Sch. 1 para. 10\(3\)\(a\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by [S.I. 2024/832 reg. 146](#)
- reg. 3(12)(d)(ia) omitted by [S.I. 2024/832 reg. 4\(a\)](#)
- reg. 4(4)(d)(ia) omitted by [S.I. 2024/832 reg. 5](#)
- reg. 43(7)(b)(ii)(bb) words omitted by [S.I. 2024/832 reg. 18\(b\)](#)
- reg. 49(1ZA)-(1ZD) inserted by [S.I. 2024/832 reg. 26\(a\)](#)
- reg. 49(3ZA) inserted by [S.I. 2024/832 reg. 26\(d\)](#)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by [S.I. 2019/1385 Sch. 1 para. 5](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by [S.I. 2019/775 reg. 57\(2\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by [S.I. 2019/775 reg. 58\(3\)](#) (This amendment not applied to [legislation.gov.uk](#). Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by [S.I. 2019/1385 Sch. 1 para. 6\(2\)](#) (This amendment not applied to [legislation.gov.uk](#). Sch. 1 paras.

2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a)

- reg. 55(1)(b)(iii)(bb) substituted by [S.I. 2024/832 reg. 43\(a\)\(ii\)](#)
- reg. 60A(10A) inserted by [S.I. 2024/832 reg. 49\(e\)](#)
- reg. 68(11H)-(A12) inserted by [S.I. 2024/832 reg. 56\(b\)](#)
- reg. 173(e) inserted by [S.I. 2017/1322 Sch. 4 para. 2\(2\)\(b\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by [S.I. 2017/1322 Sch. 4 para. 2\(3\)\(c\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by [S.I. 2017/1322 Sch. 4 para. 2\(3\)\(g\)](#) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 257(9) inserted by [S.I. 2024/832 reg. 110\(c\)](#)
- reg. 257AA257AB inserted by [S.I. 2024/832 reg. 111](#)
- reg. 327(1)(c)(va) omitted by [S.I. 2024/832 reg. 128\(a\)](#)
- reg. 346(2)(c)(iia) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 346(2)(c)(iia) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 346(2)(c)(iva) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 346(2)(c)(xviii) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 346(2)(c)(xxviii) omitted by [S.I. 2024/832 reg. 132\(b\)](#)
- reg. 347B inserted by [S.I. 2024/832 reg. 133](#)