
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

[^{F1}Medicinal products subject to additional monitoring

[^{F1}Licensing authority power in relation to medicinal products subject to additional monitoring

202A.—(1) The licensing authority may establish a list of medicinal products that are subject to additional monitoring.

(2) The list referred to in paragraph (1) is to include the names and active substances of—

- (a) medicinal products authorised in the United Kingdom that contain a new active substance which, on 1st January 2011, was not contained in any medicinal product authorised in the United Kingdom;
- (b) any biological medicinal product not covered by sub-paragraph (a) that was authorised in the United Kingdom after 1st January 2011;
- (c) medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 50I, 59(2)(b) or (c), 60 or 61(4).

(3) If the licensing authority considers it appropriate, medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 59(2)(a), (d), (e) or (f), 61(5) or 183(2), may also be included in the list referred to in paragraph (1).

(4) For medicinal products included in the list referred to in paragraph (1)—

- (a) the summary of product characteristics and the package leaflet must include a symbol and statement as follows: “▼ This medicinal product is subject to additional monitoring”; and
- (b) that symbol must be proportional to the font of the subsequent standardised text, and each side of the triangle must have a minimum length of 5 millimetres.

(5) In the cases referred to in paragraph (2)(a) and (b), the licensing authority must, unless paragraph (6) applies, remove a medicinal product from the list after five years, beginning with the day after the UK reference date referred to in regulation 193.

(6) In the cases referred to in paragraph (2)(c) and (3), the licensing authority must remove a medicinal product from the list once the condition or obligation under a provision specified in those paragraphs has been fulfilled.

(7) Until the licensing authority publishes a list of medicinal products under paragraph (1), the reference to that list is instead to be read as a reference to the list referred to in Article 23 of Regulation (EC) No 726/2004, as that list may be amended from time to time.]

Changes to legislation: *The Human Medicines Regulations 2012, Section 202A is up to date with all changes known to be in force on or before 17 August 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. (See end of Document for details) View outstanding changes*

Textual Amendments

- F1** [Reg. 202A](#) and cross-heading inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **163**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:

The Human Medicines Regulations 2012, Section 202A is up to date with all changes known to be in force on or before 17 August 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.

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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)(xviiia) 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](#)