
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[^{F1}Manufacture and distribution of medicinal products and active substances]

[^{F1}CHAPTER 2]

Manufacturing and wholesale dealing

Conditions for holding a wholesale dealer's licence

Requirement as to responsible persons

45.—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the “responsible person”) who in the opinion of the licensing authority—

- (a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and
- (b) has adequate experience relating to those activities and procedures.

[^{F1}(1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.]

(2) Those functions are—

- (a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and

[^{F2}(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

- (i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and
- (ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, [^{F3}requirements of regulation 167A,] Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.]

(3) The licence holder must notify the licensing authority of—

- (a) any change to the responsible person; and
- (b) the name, address, qualifications and experience of the responsible person.

(4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

Changes to legislation: The Human Medicines Regulations 2012, Section 45 is up to date with all changes known to be in force on or before 04 March 2025. 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

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

- (a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or
- (b) is failing to carry out the functions referred to in paragraph (2) adequately or at all.

(6) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a responsible person.

Textual Amendments

- F1** Reg. 45(1A) inserted (31.12.2022) [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **36(2)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F2** Reg. 45(2)(b) substituted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **36(3)** (as substituted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 26(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F3** Words in reg. 45(2)(b)(ii) inserted (1.1.2022) by [The Human Medicines \(Amendment\) \(Supply to Northern Ireland\) Regulations 2021 \(S.I. 2021/1452\)](#), regs. 1(2), **12**

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Changes and effects yet to be applied to :

- Sch. 3 para. 1(2)(ca)(cb) inserted by [S.I. 2025/87 reg. 34\(2\)\(b\)](#)
- Sch. 3 para. 1(3)(ba) inserted by [S.I. 2025/87 reg. 34\(3\)](#)
- Sch. 3 para. 1A1B inserted by [S.I. 2025/87 reg. 34\(4\)](#)
- Sch. 4 Pt. 1A1B inserted by [S.I. 2025/87 reg. 35](#)
- Sch. 7 para. 12B inserted by [S.I. 2025/87 reg. 36](#)
- Sch. 24 Pt. 6 inserted by [S.I. 2025/87 reg. 38](#)
- reg. 17(1A) inserted by [S.I. 2025/87 reg. 5\(3\)](#)
- reg. 17(10)(11) inserted by [S.I. 2025/87 reg. 5\(4\)](#)
- reg. 17A17B inserted by [S.I. 2025/87 reg. 6](#)
- reg. 22(1A)(1B) inserted by [S.I. 2025/87 reg. 8](#)
- reg. 26(2)(d)(e) inserted by [S.I. 2025/87 reg. 9\(b\)](#)
- reg. 27A inserted by [S.I. 2025/87 reg. 10](#)
- reg. 29(2A)-(2F) inserted by [S.I. 2025/87 reg. 11](#)
- reg. 29A29B inserted by [S.I. 2025/87 reg. 12](#)
- reg. 37(6)(ab)(ac) inserted by [S.I. 2025/87 reg. 13\(2\)\(b\)](#)
- reg. 37A37B inserted by [S.I. 2025/87 reg. 14](#)
- reg. 39(5A)-(5E) inserted by [S.I. 2025/87 reg. 15\(3\)](#)
- reg. 50(5AA)(5AB) inserted by [S.I. 2025/87 reg. 16\(3\)](#)
- reg. 50K inserted by [S.I. 2025/87 reg. 17](#)
- reg. 74A74B inserted by [S.I. 2025/87 reg. 18](#)
- reg. 167(6A)(6B) inserted by [S.I. 2025/87 reg. 19\(3\)](#)
- reg. 167G(1A)(1B) inserted by [S.I. 2025/87 reg. 20\(3\)](#)
- reg. 169(A1) inserted by [S.I. 2025/87 reg. 21](#)
- reg. 170(A1) inserted by [S.I. 2025/87 reg. 22](#)
- reg. 170A170B inserted by [S.I. 2025/87 reg. 23](#)
- reg. 171(A1) inserted by [S.I. 2025/87 reg. 24](#)
- reg. 188(1)(ca) inserted by [S.I. 2025/87 reg. 27\(2\)\(b\)](#)
- reg. 188(1A)(ba) inserted by [S.I. 2025/87 reg. 27\(3\)\(b\)](#)
- reg. 188(1B)(1C) inserted by [S.I. 2025/87 reg. 27\(4\)](#)
- reg. 202A(2)(d)(e) inserted by [S.I. 2025/87 reg. 28](#)
- reg. 257(10) inserted by [S.I. 2025/87 reg. 29](#)
- reg. 257CA inserted by [S.I. 2025/87 reg. 31](#)
- reg. 258(9) inserted by [S.I. 2025/87 reg. 32](#)
- reg. 346(2)(c)(ai)(bi) inserted by [S.I. 2025/87 reg. 33\(2\)\(a\)](#)
- reg. 346(2)(c)(iiza)-(iizc) inserted by [S.I. 2025/87 reg. 33\(2\)\(b\)](#)
- reg. 346(2)(c)(iiza)(iizb) inserted by [S.I. 2025/87 reg. 33\(2\)\(c\)](#)
- reg. 346(2)(c)(va) inserted by [S.I. 2025/87 reg. 33\(2\)\(d\)](#)
- reg. 346(2)(c)(xivb)(xivc) inserted by [S.I. 2025/87 reg. 33\(2\)\(e\)](#)
- reg. 346(2)(c)(xxviiiab)(xxviiiabc) inserted by [S.I. 2025/87 reg. 33\(2\)\(f\)](#)
- reg. 346(2)(c)(xxviiiik) inserted by [S.I. 2025/87 reg. 33\(2\)\(g\)](#)

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. 3 para. 1(2)(ca)(cb) inserted by [S.I. 2025/87 reg. 34\(2\)\(b\)](#)
- Sch. 3 para. 1(3)(ba) inserted by [S.I. 2025/87 reg. 34\(3\)](#)
- Sch. 3 para. 1A1B inserted by [S.I. 2025/87 reg. 34\(4\)](#)

- Sch. 4 Pt. 1A1B inserted by [S.I. 2025/87 reg. 35](#)
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