

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

Conditions for wholesale dealer's licence

42.—(1) Regulations 43 to 45 [^{F1}(not including regulation 43ZA)][^{F2}(in the case of a wholesale dealer's licence held in Northern Ireland) or regulations 43 to 45AA [^{F3}(including regulation 43ZA)] (in the case of a wholesale dealer's licence held in Great Britain)] apply to the holder of a wholesale dealer's licence (referred to in those regulations as “the licence holder”) and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products).

[^{F4}(2) Those provisions are regulations 43(2) and (8) and 44.]

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

^{F5}(4)

^{F6}(5)

^{F7}(6)

Textual Amendments

- F1** Words in [reg. 42\(1\)](#) inserted (1.1.2022) by [The Human Medicines \(Amendment\) \(Supply to Northern Ireland\) Regulations 2021 \(S.I. 2021/1452\)](#), regs. 1(2), **10(a)(i)**
- F2** Words in [reg. 42\(1\)](#) inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), regs. 1, **31(2)** (as amended by S.I. 2020/1488, reg. 1, [Sch. 2 para. 21\(a\)](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F3** Words in [reg. 42\(1\)](#) inserted (1.1.2022) by [The Human Medicines \(Amendment\) \(Supply to Northern Ireland\) Regulations 2021 \(S.I. 2021/1452\)](#), regs. 1(2), **10(a)(ii)**
- F4** [Reg. 42\(2\)](#) substituted (20.8.2013) by [The Human Medicines \(Amendment\) Regulations 2013 \(S.I. 2013/1855\)](#), reg. 1(1), **13**
- F5** [Reg. 42\(4\)](#) omitted (1.1.2025) by virtue of [The Human Medicines \(Amendments relating to the Windsor Framework\) Regulations 2024 \(S.I. 2024/832\)](#), regs. 1(1), **17**

Changes to legislation: *The Human Medicines Regulations 2012, Section 42 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*

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| <p>F6 Reg. 42(5) omitted (1.1.2025) by virtue of The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (S.I. 2024/832), regs. 1(1), 17</p> <p>F7 Reg. 42(6) omitted (1.1.2025) by virtue of The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (S.I. 2024/832), regs. 1(1), 17</p> |
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Changes to legislation:

The Human Medicines Regulations 2012, Section 42 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.

[View outstanding changes](#)

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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