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

[[F1]Requirement for wholesale dealers to deal only with specified persons**]**

44.—[F2](1) . . . . . .

(2) **[**[F3]The**]** licence holder must not obtain supplies of medicinal products from anyone except—

(a) the holder of a manufacturer's licence or wholesale dealer's licence in relation to products of that description;

(b) the person who holds an authorisation granted by **[**[F4]an approved country for import (in the case of a licence holder in Great Britain) or by an EEA State (in the case of a licence holder in Northern Ireland)**]** authorising the manufacture of products of the description or their distribution by way of wholesale dealing; **[**[F5]or**]**

[[F6](c) where the medicinal product is directly received—

(i) in the case of a licence holder in Great Britain, from a country that is not an approved country for import ("A"), for export to a country that is not an approved country for import ("B"), and

(ii) in the case of a licence holder in Northern Ireland, from a country other than an EEA State ("A") for export to another country other than an EEA State ("B"),

the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.**]**

[F7](d) . . . . . .

(3) Where a medicinal product is obtained in accordance with paragraph [F8]... (2)(a) or (b), the licence holder must verify that—

(a) the wholesale dealer who supplies the product complies with the principles and guidelines of good distribution practices; or

(b) the manufacturer or importer who supplies the product holds a manufacturing authorisation.

[F9](4) . . . . . .

(5) **[**F10The**]** licence holder may distribute medicinal products by way of wholesale dealing only to—

(a) the holder of a wholesale dealer's licence relating to those products;

[F11(b) the holder of an authorisation granted by—

(i) in the case of a licence holder in Great Britain, the appropriate authority of an approved country for import;

(ii) in the case of a licence holder in Northern Ireland, the competent authority of an EEA State,

that is responsible for authorising the supply of those products by way of wholesale dealing;**]**

(c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale;

(d) a person who may lawfully administer those products; or

[F12(e) in relation to supply—

(i) in the case of a licence holder in Great Britain to persons in countries other than approved countries for import, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country to which the product is supplied;

(ii) in the case of a licence holder in Northern Ireland to persons in a country other than an EEA State, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country other than an EEA State concerned.**]**

(6) Where a medicinal product is supplied to a person who is authorised or entitled to supply medicinal products to the public in accordance with paragraph F13... (5)(c) or (e), the licence holder must enclose with the product a document stating the—

(a) date on which the supply took place;

(b) name and pharmaceutical form of the product supplied;

(c) quantity of product supplied; **[**F14and**]**

(d) name and address of the licence holder**[**F15.**]**

F16(e) . . . . . .

(7) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (6) for at least five years beginning immediately after the date on which the information is supplied; and

(b) ensure that the record is available to the licensing authority for inspection.**]**

[F17(8) A licence holder in Great Britain may only obtain a medicinal product in respect of which a **[**F18UKMA(UK)(Category 2)**]** was granted under the unfettered access route if the product satisfies the definition of qualifying Northern Ireland goods.

(9) Paragraph (2)(c) does not apply to—

(a) in the case of a licence holder in Great Britain, products received from Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products received from Great Britain.

(10) Paragraph (5)(e) does not apply to—

(a) in the case of a licence holder in Great Britain, products supplied to Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products supplied to Great Britain.**]**

Textual Amendments

F1 Reg. 44 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **15**

F2 Reg. 44(1) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(2)** and reg. 44(1) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(2)**

F3 Word in reg. 44(2) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(a)** and word in reg. 44(2) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(a)**

F4 Words in reg. 44(2)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(2)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 25(a)(i)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Word in reg. 44(2) inserted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(b)** and word in reg. 44(2) inserted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(b)**

F6 Reg. 44(2)(c) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(2)(b)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(a)(ii)**)

F7 Reg. 44(2)(d) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(3)(d)** and reg. 44(2)(d) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(3)(d)**

F8 Word in reg. 44(3) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(4)** and word in reg. 44(3) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(4)**

F9 Reg. 44(4) omitted (E.W.S.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(5)** and reg. 44(4) omitted (N.I.) (1.10.2015) by virtue of The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(5)**

F10 Word in reg. 44(5) substituted (E.W.S.) (1.10.2015) by The Human Medicines (Amendment) (No. 3) Regulations 2015 (S.I. 2015/1503), regs. 1, **6(6)** and word in reg. 44(5) substituted (N.I.) (1.10.2015) by The Human Medicines (Amendment) (No.3) Regulations 2015 (S.R. 2015/354), regs. 1, **6(6)**

F11 Reg. 44(5)(b) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(3)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(b)**)

F12 Reg. 44(5)(e) substituted (31.12.2020) by S.I. 2019/775, regs. 1, **35(4)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(c)**)

F13 Word in reg. 44(6) omitted (E.W.S.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.I. 2016/186), regs. 1, **7** and word in reg. 44(6) omitted (N.I.) (1.4.2016) by virtue of The Human Medicines (Amendment) Regulations 2016 (S.R. 2016/407), regs. 1, **7**

F14 Word in reg. 44(6)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **35(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Reg. 44(6)(d): full stop substituted for word (1.1.2025) by The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (S.I. 2024/832), regs. 1(1), **20(a)(i)**

F16 Reg. 44(6)(e) 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), **20(a)(ii)**

F17 Reg. 44(8)-(10) inserted (31.12.2020) by S.I. 2019/775, regs. 1, **35(6)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 25(e)**)

F18 Words in reg. 44(8) substituted (1.1.2025) by The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (S.I. 2024/832), regs. 1(1), **20(b)**

Changes to legislation:
The Human Medicines Regulations 2012, Section 44 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)(iiiza)(iiizb) 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)(xxviiiazb)(xxviiiazc) inserted by S.I. 2025/87 reg. 33(2)(f)
- reg. 346(2)(c)(xxviiik) 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
- 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)(iiiza)(iiizb) 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)(xxviiiazb)(xxviiiazc) inserted by S.I. 2025/87 reg. 33(2)(f)
- reg. 346(2)(c)(xxviiik) inserted by S.I. 2025/87 reg. 33(2)(g)