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

Grant etc of licences

[[F1]Wholesale dealing in medicinal products**]**

18.—(1) A person may not except in accordance with a licence (a "wholesale dealer's licence")—

(a) distribute a medicinal product by way of wholesale dealing; [F2]...

(b) possess a medicinal product for the purpose of such **[**[F3]distribution; [F4]...**]**

[[F5](c) import a medicinal product into Great Britain from an approved country for import**][**[F6]; or

(d) supply a listed NIMAR product from Great Britain to Northern Ireland.**]**

(2) Paragraph (1)—

(a) does not apply—

(i) to anything done in relation to a medicinal product by the holder of a manufacturer's licence in respect of that product,

(ii) where the product concerned is an investigational medicinal product, or

(iii) if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source; and

(b) is subject to regulation 19.

[[F7](2A) Paragraph (1)(c) does not apply to imports into Great Britain from an EEA State of medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(2B) For the purposes of paragraph (2A) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.**]**

(3) Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, is not to be taken to be in accordance with a wholesale dealer's licence unless the distribution is carried on, or as the case may be the product held, at premises located in the UK and specified in the licence.

(4) In these Regulations a reference to distributing a product **[**F8(including a listed NIMAR product)**]** by way of wholesale dealing is a reference to—

(a) selling or supplying it; or

(b) procuring or holding it or exporting it for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (5).

(5) Those purposes are—

(a) selling or supplying the product; or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

[F9(6) A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession of a medicinal product for the purpose of such distribution, unless—

(a) in the case of a product for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration is in force in respect of the product, F10...

(b) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK) F11..., Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product, **[**F12or

(c) in the case of a listed NIMAR product, a UKMA(GB) or UKMA(UK) is in force in respect of the product,**]**

but this is subject to the exceptions in regulation 43(6).**]**

F13(7) . . . . . **]**

Textual Amendments

F1 Reg. 18 substituted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **5**

F2 Word in reg. 18(1)(a) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 18(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F4 Word in reg. 18(1)(b) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(i)**

F5 Reg. 18(1)(c) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2)(c)** (as amended S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(a)(i)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Reg. 18(1)(d) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(a)(ii)**

F7 Reg. 18(2A)(2B) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(2A)** (as inserted by S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 18(4) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(b)**

F9 Reg. 18(6) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **15(3)** (as substituted by (S.I. 2020/1488, reg. 1, **Sch. 2 para. 10(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F10 Word in reg. 18(6)(a) omitted (1.1.2022) by virtue of The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(i)**

F11 Words in reg. 18(6)(b) 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), **11(a)**

F12 Reg. 18(6)(c) and word inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **5(c)(ii)**

F13 Reg. 18(7) 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), **11(b)**

Changes to legislation:
The Human Medicines Regulations 2012, Section 18 is up to date with all changes known to be in force on or before 24 February 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)
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- 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)