STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[F1Manufacture and distribution of medicinal products and active substances]

[F1CHAPTER 2]

Manufacturing and wholesale dealing

Conditions for holding a wholesale dealer's licence

[F1Requirement as to responsible persons where licence holder imports from an approved country for import

45AA.—(1) Subject to paragraph (2), this regulation applies to a licence holder in Great Britain where the licence holder imports a medicinal product from an approved country for import under a wholesale dealer's licence.

(2) The requirements of this regulation do not apply where an unlicensed medicinal product falling under paragraph (1) is imported—

(a) from an approved country for import for the sole purpose of distribution by way of wholesale dealing as a special medicinal product; or

(b) for the sole purpose of wholesale distribution of that product to a person in a country other than an approved country for import.

(3) 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 (import)") whose name is included in the register established under regulation 45AB.

(4) A responsible person (import) must—

(a) carry out the functions under regulation 45(2), unless a responsible person under regulation 45 is performing those functions in respect of the licence; ...

(b) ensure that there is appropriate evidence to confirm that each production batch of a medicine imported from an approved country for import under the licence has been certified as provided for in Article 51 of the 2001 Directive, or such equivalent certification procedure as applies in the approved country for import; and

(c) ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by—

(i) the appropriate authority, or

(ii) where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority's own examination.

(5) The licensing authority must publish guidance on the documentation that it considers to be appropriate evidence for the purposes of paragraph (4)(b).

(6) Guidance published under paragraph (5) may be taken into account by the licensing authority in determining whether it considers there has been a failure to comply with this regulation.

(7) The licence holder must apply to vary the licence if a change is proposed to the responsible person (import).

(8) The licence holder must not permit any person to act as a responsible person (import) other than the person named in the licence.

(9) Paragraph (10) applies if—

(a) the person acting as responsible person (import) in respect of the licence is no longer included in the register under 45AB;

(b) the licensing authority thinks, after giving the licence holder and a person acting as a responsible person (import) the opportunity to make representations (orally or in writing), that the responsible person (import) is failing to carry out the functions referred to in paragraph (4) adequately or at all.

(10) Where this paragraph applies the licensing authority—

(a) must notify the licence holder in writing that the person is not permitted to act as a responsible person (import) in respect of that licence; and

(b) may, subject to regulation 45AB(3)(b), remove that person's name from the register under regulation 45AB.

(11) In this regulation, "unlicensed medicinal product" means a medicinal product in respect of which—

(a) there is no marketing authorisation, within the meaning of the 2001 Directive, in any EEA State in respect of that product, where the product is imported from an approved country for import that is an EEA State; or

(b) there is no licence or authorisation in respect of that product as regards its sale or supply in the approved country for import, where the product is imported from an approved country for import that is not an EEA State.**]**

Textual Amendments

F1 Regs. 45AA, 45AB inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **37** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 27**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
The Human Medicines Regulations 2012, Section 45AA 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
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- 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)
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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)