
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}Approved country for import

18A.—(1) The licensing authority must—

- (a) publish a list of countries from which medicinal products may be imported under a wholesale dealing licence (“approved country for import list”); and
- (b) only include in that list a country which is included in the approved country for batch testing list.

(2) In order to determine whether a country should be included in the approved country for import list, the licensing authority may, in particular, take into account—

- (a) the country's system for ensuring that each batch of a medicinal product has been manufactured and checked in accordance with the requirements of its legislation and any authorisation in respect of that product;
- (b) the country's rules for good distribution practice;
- (c) the regularity of inspections to verify compliance with good distribution practice;
- (d) the effectiveness of enforcement of good distribution practice;
- (e) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers and distributors of medicinal products;
- (f) any on-site review of that country's regulatory system undertaken by the licensing authority;
- (g) any on-site inspection of a manufacturing site in that country observed by the licensing authority; and
- (h) any other relevant documentation available to the licensing authority.

(3) The licensing authority must—

- (a) remove a country from the approved country for import list if that country is removed from the approved country for batch testing list;
- (b) in any event review the countries it has included in the approved country for import list to determine if it is still satisfied that the country should remain on that list, and if it is not so satisfied, remove that country from the list; and

Changes to legislation: The Human Medicines Regulations 2012, Section 18A 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

- (c) undertake that review at least every three years beginning with the date on which that country is included in that list.]

Textual Amendments

- F1** [Reg. 18A](#) inserted (31.12.2020) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/775), regs. 1, **16**; 2020 c. 1, Sch. 5 para. 1(1)

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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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