STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

Supply to fulfil special patient needs

167.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to a medicinal product (a "special medicinal product") if—

(a) the medicinal product is supplied in response to an unsolicited order;

(b) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;

(c) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and

(d) the following conditions are met.

(2) Condition A is that the medicinal product is supplied—

(a) to a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber; or

(b) for use under the supervision of a pharmacist in a registered pharmacy, a hospital or a health centre.

(3) Condition B is that no advertisement relating to the medicinal product is published by any person.

(4) Condition C is that—

(a) the manufacture and assembly of the medicinal product are carried out under such supervision; and

(b) such precautions are taken,

as are adequate to ensure that the medicinal product meets the specification of the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber who requires it.

(5) Condition D is that written records of the manufacture or assembly of the medicinal product in accordance with condition C are maintained and are available to the licensing authority or to the enforcement authority on request.

(6) Condition E is that if the medicinal product is manufactured or assembled in the United Kingdom **[**F1, imported into Northern Ireland from a country other than an EEA State or Great Britain,

or imported into Great Britain from a country other than an approved country for import or Northern Ireland**]**—

(a) it is manufactured, assembled or imported by the holder of a manufacturer's licence that relates specifically to the manufacture, assembly or importation of special medicinal products; or

(b) it is manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorisation granted by the licensing authority for the purposes of regulation 36 of the Clinical Trials Regulations.

(7) Condition F is that if the product is **[**F2imported into Northern Ireland from an EEA State or imported into Great Britain from a country other than an approved country for import**]**—

[F3(a) it is manufactured or assembled in that State or country (as appropriate) by a person who is the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, the provisions of the 2001 Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, in accordance with the provisions applicable in that country; or**]**

[F4(b) it is manufactured or assembled as an investigational medicinal product in that State or country (as appropriate) by the holder of an authorisation in relation to its manufacture or assembly in accordance with—

(i) in the case of a product for sale or supply in Northern Ireland, Article 13 of the Clinical Trials Directive as implemented in that State, and

(ii) in the case of a product for sale or supply in Great Britain, regulations 13 and 43 of the Clinical Trials Regulations,**]**

[F5and it is imported by the holder of a wholesale dealer's licence in relation to the product in question.**]**

(8) Condition G is that if the product is distributed by way of wholesale dealing by a person ("P"), who has not, as the case may be, manufactured, assembled or imported the product in accordance with paragraph (6)(a) or (7)(a), P must be the holder of a wholesale dealer's licence in relation to the product in question.

(9) In this regulation "publish" has the meaning given in regulation 277(1) (interpretation: Part 14 advertising).

Textual Amendments

F1 Words in reg. 167(6) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(a)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F2 Words in reg. 167(7) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(i)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F3 Reg. 167(7)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(ii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F4 Reg. 167(7)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 135ZA(b)(iii)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 102**)

F5 Words in reg. 167(7)(b) inserted (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.I. 2017/715), regs. 1, **5(2)(b)** and words in reg. 167(7)(b) inserted (N.I.) (1.10.2017) by The Human Medicines (Amendment) Regulations 2017 (S.R. 2017/241), regs. 1, **5(2)(b)**

Changes to legislation:
The Human Medicines Regulations 2012, Section 167 is up to date with all changes known to be in force on or before 26 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(6) words inserted by S.I. 2025/87 reg. 19(2)
- reg. 167(6A)(6B) inserted by S.I. 2025/87 reg. 19(3)
- reg. 167(7) words omitted by S.I. 2025/87 reg. 19(4)
- 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)
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- 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
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- 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
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- 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)