STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Exceptions

Exempt advanced therapy medicinal products

171.—(1) The prohibitions in regulation 46 (requirement for authorisation) do not apply in relation to an advanced therapy medicinal product (an "exempt advanced therapy medicinal product") if the following conditions are met.

(2) Condition A is that the product is prepared—

(a) on a non-routine basis;

(b) in the United Kingdom; and

(c) according to specific quality standards equivalent to those provided for advanced therapy medicinal products authorised under **[**[F1]—

(i) in the case of a product for sale or supply in Northern Ireland, Regulation (EC) No 726/2004, and

(ii) in the case of a product for sale or supply in Great Britain, regulation 49(1).**]**

(3) Condition B is that the product is used—

(a) in a hospital in the United Kingdom;

(b) under the exclusive professional responsibility of a doctor; and

(c) in order to comply with an individual medical prescription for a product made to order for an individual patient.

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

(5) Condition D is that the sale or supply of the medicinal product is in response to an unsolicited order.

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

Textual Amendments

F1 Reg. 171(2)(c)(i)(ii) substituted for words in reg. 171(2)(c) (31.12.2020) by S.I. 2019/775, **reg. 137** (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 105**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
The Human Medicines Regulations 2012, Section 171 is up to date with all changes known to be in force on or before 24 September 2024. 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 :

- reg. 171(2)(c) words substituted by S.I. 2019/775 reg. 137 (This amendment not applied to legislation.gov.uk. Reg. 137 amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 105)
- reg. 171(2)(c) words substituted by S.I. 2024/832 reg. 72

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. 11 para. 1(1)(d)-(f) inserted by S.I. 2019/775 reg. 63(2)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by S.I. 2024/832 reg. 142(e)
- Sch. 24 Pt. 1 para. 23 words omitted by S.I. 2024/832 reg. 142(f)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(4) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by S.I. 2024/832 reg. 146
- reg. 3(12)(d)(ia) omitted by S.I. 2024/832 reg. 4(a)
- reg. 4(4)(d)(ia) omitted by S.I. 2024/832 reg. 5
- reg. 43(7)(b)(ii)(bb) words omitted by S.I. 2024/832 reg. 18(b)
- reg. 49(1ZA)-(1ZD) inserted by S.I. 2024/832 reg. 26(a)
- reg. 49(3ZA) inserted by S.I. 2024/832 reg. 26(d)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by S.I. 2019/1385 Sch. 1 para. 5 (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by S.I. 2019/775 reg. 57(2) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)
- reg. 53(2)-(2C) substituted for reg. 53(2) by S.I. 2019/775 reg. 58(3) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by S.I. 2019/1385 Sch. 1 para. 6(2) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 55(1)(b)(iii)(bb) substituted by S.I. 2024/832 reg. 43(a)(ii)

- reg. 60A(10A) inserted by S.I. 2024/832 reg. 49(e)
- reg. 68(11H)-(A12) inserted by S.I. 2024/832 reg. 56(b)
- reg. 173(e) inserted by S.I. 2017/1322 Sch. 4 para. 2(2)(b) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(c) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(g) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 257(9) inserted by S.I. 2024/832 reg. 110(c)
- reg. 257AA257AB inserted by S.I. 2024/832 reg. 111
- reg. 327(1)(c)(va) omitted by S.I. 2024/832 reg. 128(a)
- reg. 346(2)(c)(iia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iiia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iva) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xviia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xxviiij) omitted by S.I. 2024/832 reg. 132(b)
- reg. 347B inserted by S.I. 2024/832 reg. 133