STATUTORY INSTRUMENTS

2016 No. 190

The Medicines (Products for Human Use) (Fees) Regulations 2016

PART 2

Capital Fees for Pre-Application Meetings

Interpretation of Part 2

3. In this Part—

"EU marketing authorisation" means—

(a) a United Kingdom marketing authorisation granted by the licensing authority under Part 5 (marketing authorisations) of the Human Medicines Regulations;

(b) a marketing authorisation granted by the competent authority of an EEA State other than the United Kingdom in accordance with the 2001 Directive; or

(c) a European Union marketing authorisation; and

"relevant medicinal product" means a medicinal product for human use to which the provisions of the 2001 Directive apply.

Fee for scientific advice: application for, or variation to, EU marketing authorisation

4. Unless regulation 5 applies, the fee payable by a person with whom the licensing authority holds a meeting in order to provide scientific advice with a view to that person making an application for an EU marketing authorisation or an application for the variation of an EU marketing authorisation, is—

(a) £2,201, if the advice provided at that meeting consists of advice in connection with—

(i) quality development only; or

(ii) safety development only;

(b) £2,763, if the advice provided at that meeting consists only of advice in connection with clinical development;

(c) £3,061, if the advice provided at that meeting consists only of advice in connection with quality and safety development;

(d) £3,624, if the advice provided at that meeting consists of advice in connection with—

(i) quality and clinical development; or

(ii) safety and clinical development;

(e) £4,487, if the advice provided at that meeting consists of advice in connection with quality, safety and clinical development.

Fee for scientific advice: classification of a medicinal product

5.—(1) The fee payable by a person with whom the licensing authority holds a meeting to provide scientific advice in connection with the classification of a relevant medicinal product, is—

(a) £2,763, if the advice relates to a product which, if reclassified, will be available on general sale; and

(b) £3,624, if the advice relates to a product which, if reclassified, will be available without a prescription from a pharmacy.

(2) For the purposes of this regulation, a product is on general sale if it is a medicinal product subject to general sale within the meaning of regulation 5(1) of the Human Medicines Regulations (classification of medicinal products for general sale).

Fee for advertising advice

6. The fee payable by the holder of a marketing authorisation with whom the licensing authority holds a meeting in order to provide advice before the publication of advertising of a medicinal product by that holder's undertaking on whether that advertising conforms to the requirements of Title VIII of the 2001 Directive, is £2,201.

Fee for pharmacovigilance advice

7.—(1) The fee payable by a person with whom the licensing authority holds a meeting in order to provide pharmacovigilance advice is—

(a) £3,624, in a case where the time taken by the licensing authority to prepare for and attend the meeting is more than six hours;

(b) £3,061, in any other case.

(2) The time taken by the licensing authority for the purposes of paragraph (1) shall be the total time spent by each individual engaged in preparing for or attending the meeting on behalf of the licensing authority.

Fee for advice on labelling or leaflets

8. The fee payable by the holder of one or more marketing authorisations with whom the licensing authority holds a meeting in order to provide advice on proposed changes to the labelling or the package leaflets of the medicinal products to which those authorisations relate, is £2,201.

Fee for regulatory advice

9. The fee payable by the holder of a marketing authorisation with whom the licensing authority holds a meeting in order to provide regulatory advice to that person, is £2,763.

Fee for advice for other purposes

10.—(1) Unless paragraph (4) applies, the fee payable by a person specified in paragraph (2) with whom the licensing authority holds a meeting for a purpose specified in paragraph (3) is £4,451.

(2) A person who—

(a) is, or is to be, a sponsor of a clinical trial;

(b) manufactures medicinal products;

(c) is, or is to be, responsible for placing medicinal products on the market; or

(d) acts on behalf of, or provides advice or assistance to, a person referred to in sub-paragraphs (a) to (c),

is a specified person for the purpose of paragraph (1).

(3) A meeting referred to in paragraph (1) is for a specified purpose if it is held to provide advice in relation to—

(a) scientific or regulatory issues relating to the development of a medicinal product or a type of medicinal product;

(b) the design of pharmaceutical or pre-clinical tests, or clinical trials, for a medicinal product or a type of medicinal product;

(c) the management of risk in relation to a medicinal product or a type of medicinal product which is under development, or is being marketed in the European Union; or

(d) other scientific or regulatory issues relating to a medicinal product or a type of medicinal product after an EU marketing authorisation has been granted for that product or a product of that type.

(4) Paragraph (1) does not apply in the case of a meeting where the purpose of such a meeting is to provide only advice specified in regulations 4 to 9.

(5) In this regulation—

"Directive 93/42/EEC" means Council Directive 93/42/EEC concerning medical devices [F1];

"medical device" has the same meaning as in Article 1(2)(a) of Directive 93/42/EEC;

"medicinal product" includes a substance incorporated in a medical device which, if used separately, may be considered to be a medicinal product as defined in Article 1(2) of the 2001 Directive;

"regulatory issues" means issues relating to the application of any EU instrument relating to EU marketing authorisations or to medical devices, or any enactment which implements such an instrument;

"risks" means any risk relating to the quality, safety or efficacy of a medicinal product as regards patients' health or public health, or any risk of undesirable effects on the environment;

"sponsor" shall be interpreted in accordance with regulation 3 (sponsor of a clinical trial) of the Clinical Trials Regulations [F2];

and a reference to the development of a medicinal product or a type of medicinal product is a reference to development for the purposes of—

(a) obtaining an EU marketing authorisation, or making a variation to an EU marketing authorisation, for that product or a product of that type; [F3]...

(b) obtaining a design-examination certificate of the type mentioned in paragraph 4.3 of Annex II to Directive 93/42/EEC or a type-examination certificate of the type mentioned in paragraph 5 of Annex III to that Directive, for a medical device incorporating that product or a product of that type**[**[F4]; or

(c) obtaining an EU technical documentation assessment certificate or EU type-examination certificate of the type mentioned in section 5 of Annex IX and section 6 of Annex X of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, for a medical device incorporating that product or a product of that type.**]**

Textual Amendments

F1 OJ No L 169, 12.7.1993, p1. This Directive has been amended by Directive 98/79/EC of the European Parliament and of the Council (OJ No L 331, 7.12.1998, p1), Directive 2000/70/EC of the European Parliament and of the Council (OJ No L 313, 13.12.2000, p22), Directive 2001/104/EC of the European Parliament and of the Council (OJ No L 6, 10.1.2002, p50), Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ No L 284, 31.10.2003, p1) and Directive 2007/47/EC of the European Parliament and of the Council (OJ No L 247, 21.9.2007, p21).

F2 Regulation 3 has been amended by S.I. 2006/1928.

F3 Word in reg. 10(5)(a) omitted (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **41(a)**

F4 Reg. 10(5)(c) and word inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **41(b)**

Modifications etc. (not altering text)

C1 Reg. 10(5) modified (31.12.2020) by S.I. 2002/618, **reg. 4T(2)** (as inserted by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2** and S.I. 2021/873, reg. 1(1), **Sch. 1 para. 7(a)(ii)**); 2020 c. 1, **Sch. 5 para. 1(1)**)

[F5Waiver for advice given to small and medium companies

10A.—(1) The fee payable in connection with a meeting mentioned in any of regulations 4 to 10 is waived where the person by whom the fee would otherwise be payable is established in the United Kingdom and is—

(a) a small company, or

(b) a medium-sized company.

(2) In this regulation, "small company" and "medium-sized company" have the same meanings as in sections 382 and 465 of the Companies Act 2006 respectively.**]**

Textual Amendments

F5 Reg. 10A inserted (31.12.2020) by S.I. 2019/775, **Sch. 1 para. 1ZA** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(a)**)

Time for payment of fees under regulations 4 to 10

11. All sums payable by way of fees under regulations 4 to 10 must be paid within a period of 14 days, commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Products for Human Use) (Fees) Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

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. 2 para. 35A inserted by S.I. 2023/314 reg. 24(14)
- Sch. 2 para. 27(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(i)
- Sch. 2 para. 27(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(ii)
- Sch. 2 para. 27(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iii)
- Sch. 2 para. 27(2)(d)(i) sum substituted by S.I. 2023/314 reg. 24(5)(a)(iv)
- Sch. 2 para. 27(3)(a)(i) sum substituted by S.I. 2023/314 reg. 24(5)(b)
- Sch. 2 para. 28(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(i)
- Sch. 2 para. 28(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(2)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(a)(ii)
- Sch. 2 para. 28(3)(b)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28(3)(c)(i) sum substituted by S.I. 2023/314 reg. 24(6)(b)
- Sch. 2 para. 28A(1)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(a)
- Sch. 2 para. 28A(2)(a)-(c) sum substituted by S.I. 2023/314 reg. 24(7)(b)
- Sch. 2 para. 56(c) sum substituted by S.I. 2023/314 reg. 24(27)(b)
- Sch. 2 para. 57A(a) sum substituted by S.I. 2023/314 reg. 24(29)(a)
- Sch. 2 para. 57A(b) sum substituted by S.I. 2023/314 reg. 24(29)(b)
- Sch. 2 para. 57A(c) sum substituted by S.I. 2023/314 reg. 24(29)(c)
- Sch. 2 para. 57A(d) sum substituted by S.I. 2023/314 reg. 24(29)(d)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(v)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(vii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(viii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(a)(ix)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(i)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(ii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iii)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(iv)
- Sch. 2 para. 57B(4) sum substituted by S.I. 2023/314 reg. 24(30)(b)(v)
- Sch. 4 para. 15(3) inserted by S.I. 2023/314 reg. 26(8)
- reg. 19A(1) sum substituted by S.I. 2023/314 reg. 13(a)
- reg. 19A(2)(a) sum substituted by S.I. 2023/314 reg. 13(b)
- reg. 19A(2)(b) sum substituted by S.I. 2023/314 reg. 13(c)
- reg. 19B sum substituted by S.I. 2023/314 reg. 14
- reg. 19C(2)(a) sum substituted by S.I. 2023/314 reg. 15(a)(i)
- reg. 19C(2)(b) sum substituted by S.I. 2023/314 reg. 15(a)(ii)
- reg. 19C(2)(c) sum substituted by S.I. 2023/314 reg. 15(a)(iii)
- reg. 19C(3)(a) sum substituted by S.I. 2023/314 reg. 15(b)(i)
- reg. 19C(3)(b) sum substituted by S.I. 2023/314 reg. 15(b)(ii)
- reg. 19C(3)(c) sum substituted by S.I. 2023/314 reg. 15(b)(iii)
- reg. 19E(2)(a) sum substituted by S.I. 2023/314 reg. 16(a)
- reg. 19E(2)(b) sum substituted by S.I. 2023/314 reg. 16(b)

– reg. 19EA inserted by S.I. 2023/314 reg. 17