STATUTORY INSTRUMENTS

2016 No. 190

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

PART 5

Capital Fees for Applications for Variations of Authorisations, Registrations and Licences and for Associated Compliance Activities

Fees for variations of authorisations, registrations and licences

19.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the fee mentioned in paragraph (2) applies for an application—

(a) under the Human Medicines Regulations, under regulation—

(i) 29 (variation of licence on application of holder);

[F1(ii) 65C (variation of a UK marketing authorisation)**]**

(iii) 135 (revocation, variation and suspension of a traditional herbal registration) but only in relation to a variation of such a registration;

(b) to vary a parallel import licence;

(c) to vary a broker's registration or an active substance registration;

(d) under regulation 44 (variation of manufacturing authorisation) of the Clinical Trials Regulations F2 for the variation of a manufacturing authorisation.

[F3(e) under Commission Regulation (EC) No 1234/2008 for the variation of a UKMA(UK) or UKMA(NI).**]**

(2) The fee referred to in paragraph (1) is—

(a) the fee prescribed in Part 4 of Schedule 2 in connection with the application; and

(b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 30, 32, 33, 35 and 37.

(3) Unless regulation 32 applies, the fee referred to in paragraph (1) is payable by the applicant.

[F4(4) The reference in paragraph (1)(a)(ii) to an application under regulation 65C of the Human Medicines Regulations includes a reference to an application or notification submitted under paragraph 11(7) or 12(3) of Schedule 33A to the Human Medicines Regulations, or an application or notification which would have been submitted under those paragraphs but for its earlier submission in accordance with paragraph 13(1)(a) of that Schedule.**]**

F1 Reg. 19(1)(a)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 1(a)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

F2 Regulation 44 has been amended by S.I. 2006/1928 and S.I. 2013/532.

F3 Reg. 19(1)(e) inserted (31.12.2020) by S.I. 2019/775, **Sch. 1 para. 1(aa)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(b)**)

F4 Reg. 19(4) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 1(b)** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

[F5Fees for certification of plasma master files

19A.—(1) The fee payable by a person who submits a plasma master file to the licensing authority for scientific and technical evaluation in accordance with paragraph 1.1(c), second indent, of Part III of Annex I to the 2001 Directive, is £8,309.

(2) The fee payable by a person who submits a plasma master file to the licensing authority for re-certification in accordance with paragraph 1.1(c), third indent, of Part III of Annex I to the 2001 Directive is—

(a) £277, where there are no changes to the plasma master file other than an update to epidemiological data; or

(b) £734, in any other case.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fee for certification of vaccine antigen master files

19B. The fee payable by a person who submits a vaccine antigen master file to the licensing authority for scientific and technical evaluation in accordance with paragraph 1.2(c), first indent, of Part III of Annex I to the 2001 Directive, is £8,309.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fees for assessment of post-authorisation safety studies

19C.—(1) This regulation applies to post-authorisation safety studies initiated, managed or financed by the holder of a marketing authorisation in compliance with obligations imposed under regulation 59 or 61 of the Human Medicines Regulations.

(2) The fee payable by the holder of a marketing authorisation upon submission of the draft protocol for a post-authorisation safety study in accordance with regulation 199(2) of the Human Medicines Regulations—

(a) where the authorisation for the medicinal product concerned is a UKMA(GB) granted under the unfettered access route or a UKMA(GB) granted where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), and provided a corresponding draft protocol has been submitted in respect of the related European Union marketing authorisation or UKMA(NI) for the same product, is £734;

(b) where sub-paragraph (a) does not apply and—

(i) the study is to be conducted in the United Kingdom only; or

(ii) the authorisation for the product which is the subject of the study authorises sale or supply in Great Britain only,

is £8,309; and

(c) in any other case, is £734.

(3) The fee payable by the holder of a marketing authorisation upon submission of the final study report for a post-authorisation safety study in accordance with regulation 201(2) of the Human Medicines Regulations—

(a) where the authorisation for the medicinal product concerned is a UKMA(GB) granted under the unfettered access route or a UKMA(GB) granted where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), and provided a corresponding final study report has been submitted in respect of the related European Union marketing authorisation or UKMA(NI) for the same product, is £734;

(b) where sub-paragraph (a) does not apply and—

(i) the study is to be conducted in the United Kingdom only; or

(ii) the authorisation for the product which is the subject of the study authorises sale or supply in Great Britain only,

is £8,309; and

(c) in any other case, is £734.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fee for carrying out a major safety review

19D.—(1) Where the licensing authority conducts a major safety review of a United Kingdom marketing authorisation or traditional herbal registration, or a set of such marketing authorisations or traditional herbal registrations, under regulation 196 of the Human Medicines Regulations, a fee is payable in accordance with Part 6A of Schedule 2.

(2) Unless paragraph (3) applies, the fee referred to in paragraph (1) is payable by the holder of the marketing authorisation or registration to which the review relates.

(3) Where the review relates to two or more authorisations or registrations the fee referred to in paragraph (1) is to be divided by the number of authorisations or registrations forming part of the review ("relevant authorisation or registration") and each holder of a relevant authorisation or registration must pay that reduced fee in respect of each relevant authorisation or registration it holds.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fee for assessment of periodic safety update reports

19E.—(1) This regulation applies where—

(a) a periodic safety update report has been submitted to the licensing authority under regulation 191 or 192 of the Human Medicines Regulations; and

(b) that periodic safety update report relates to a medicinal product which has a UK reference date within the meaning of regulation 193 of the Human Medicines Regulations.

(2) Where this regulation applies, the fee payable by the holder of a marketing authorisation or traditional herbal registration to which the periodic safety update report relates is—

(a) £890, in the case where no other periodic safety update reports relating to medicinal products with the same UK reference date are submitted; and

(b) £445, in any other case.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fee for testing of samples by the appropriate authority

19F.—(1) Where a sample from a batch of a medicinal product is submitted to the appropriate authority in accordance with a batch testing condition imposed under regulation 60A of the Human Medicines Regulations, the fee payable by the holder of the marketing authorisation to which the medicinal product relates is the fee prescribed in Part 6B of Schedule 2 in connection with that submission.

(2) The fee payable by an applicant for a certified copy of a certificate confirming that the appropriate authority is satisfied that the batch is in conformity with the approved specifications is £50.

(3) In this regulation, and in Part 6B of Schedule 2, "appropriate authority" and "batch testing condition" have the same meaning as in regulation 60A of the Human Medicines Regulations.

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Time for payment of fees under regulations 19A to 19F

19G. All sums payable by way of fees under regulations 19A to 19F are payable on invoice.**]**

F5 Regs. 19A-19G inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 2** (with Sch. 1 para. 11) (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 188(c)(i)(aa)(bb)**); 2020 c. 1, Sch. 5 para. 1(1)

Fees for amendments to clinical trial authorisations

20.—(1) A person who sends a valid notice of amendment under regulation 24 (amendments by the sponsor) of the Clinical Trials Regulations [F6] relating to amendment of the protocol or the dossier related to a request for authorisation in accordance with paragraphs 10 or 11 of Part 2 of Schedule 3 (request for authorisation) to those Regulations must pay the fees mentioned in paragraph (2).

(2) The fees referred to in paragraph (1) are—

(a) the fee prescribed in paragraph 49 of Schedule 2 in connection with that amendment; and

(b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 30, 32, 33, 35 and 37.

F6 Regulation 24 has been amended by S.I. 2006/1928 and S.I. 2013/532.

Fees for notification of changes and reports for broker's registrations

21.—(1) A fee of £257 is payable by the holder of a broker's registration who provides, in accordance with any Regulations in connection with that registration—

(a) any report that must be submitted relating to that registration, or

(b) any notification that must be submitted about changes relating to that registration.

(2) The fee in paragraph (1) is payable for each report or notification of change made in connection with that broker's registration.

Fees for notification of changes and compliance Reports for active substance registrations

22.—(1) A fee of £257 is payable by the holder of an active substance registration who provides, in accordance with any Regulations in connection with that registration—

(a) any report that must be submitted relating to that registration, or

(b) any notification that must be submitted about changes relating to that registration.

(2) The fee in paragraph (1) is payable for each report or notification of change made in connection with that active substance registration.

Applications for multiple variations

23.—(1) Unless paragraph (3) or (5) applies, a separate fee is payable in respect of each application to vary each term of a marketing authorisation.

(2) Unless paragraph (5) applies, a separate fee is payable in respect of each variation of each provision of a traditional herbal registration, manufacturing authorisation or licence applied for in any one application.

(3) A separate fee is not payable for each application to vary a term of a marketing authorisation which—

(a) falls within the same type of group application; or

(b) the licensing authority—

[F7(i) have agreed—

(aa) in the case of a UKMA(NI) or UKMA(UK), in consultation with member States concerned and in accordance with Article 7(2)(c) of Commission Regulation (EC) No 1234/2008, should be subject to the procedure for grouping of variations within the meaning of that Article;

(bb) in the case of a UKMA(GB), should be subject to the procedure for grouping of variations within the meaning of paragraph 5(2)(c) of Schedule 10A to the Human Medicines Regulations; and**]**

(ii) have agreed fall, or should be treated as falling, within the same type of group application.

(4) For the purposes of paragraph (3) the reference to a group application means an application which is a—

(a) Minor Variation (Type IB) Group Application;

(b) Major Variation (Type II) Group Application;

(c) Major Variation (Type II) Complex Group Application; or

(d) Major Variation (Type II) Extended Complex Group Application.

(5) A separate fee is not payable for a variation which is wholly consequential upon another variation of a provision of a marketing authorisation, traditional herbal registration, manufacturing authorisation or licence which is applied for in the same application.

[F8(6) In a case where a recommendation on the classification of a variation is made in accordance with—

(a) in the case of a UKMA(NI) or UKMA(UK), Article 5 of Commission Regulation (EC) No 1234/2008; or

(b) in the case of a UKMA(GB), paragraph 3 of Schedule 10A to the Human Medicines Regulations,

the fee payable for the application made in respect of that variation is the appropriate fee for the classification given to the variation or, as the case may be, the appropriate fee which arises as a consequence of the classification given to the variation.**]**

(7) In this regulation and Part 4 of Schedule 2—

"Major Variation (Type II) Group Application" means an application for several variations to one marketing authorisation and—

(a) at least one of the variations is a major variation of type II;

(b) **[**F9subject to sub-paragraph (c), the variations fall—

(i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(c) the variations do not include a variation—

(i) **[**F10of a kind referred to—

(aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to Commission Regulation (EC) No 1234/2008;

(bb) in the case of UKMA(GB), in paragraph 5(3)(a) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(ii) which relates to a change which is referred to in paragraph 23 of Schedule 2 (Type II Complex Variation Application); or

(iii) of a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2 (Extended Type II Complex Variation Application); and

(d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB;

"Major Variation (Type II) Complex Group Application" means an application for several variations to one marketing authorisation and—

(a) at least one of the variations relates to one or more of the changes referred to in paragraph 23 of Schedule 2;

(b) **[**F11subject to sub-paragraph (c), the variations fall—

(i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2) (b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(c) the variations do not include a variation of—

(i) **[**F12of a kind referred to—

(aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to Commission Regulation (EC) No 1234/2008;

(bb) in the case of a UKMA(GB), in paragraph 5(3)(a) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(ii) a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2; and

(d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB or one or more major variations of type II;

"Major Variation (Type II) Extended Complex Group Application" means an application for several variations to one marketing authorisation and—

(a) at least one of the variations is a variation to a marketing authorisation so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 2;

(b) **[**F13subject to sub-paragraph (c), the variations fall—

(i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2) (b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(c) **[**F14the variations do not include a variation of a kind referred to—

(i) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 of Annex III to Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), in paragraph 5(3)(a) of Schedule 10A to the Human Medicines Regulations; and**]**

(d) the variations may include minor variations of type IA, minor variations of type IB or other major variations of type II or a variation relating to a change referred to in paragraph 23(a), (b) or (c) of Schedule 2;

[F15"major variation of type II"—

(a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(3) of Commission Regulation (EC) No 1234/2008; and

(b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations;**]**

"Minor Variation (Type IB) Group Application" means an application for several variations to one marketing authorisation and—

(a) at least one of the variations is a minor variation of type IB;

(b) **[**F16subject to sub-paragraph (c), the variations fall—

(i) in the case of a UKMA(NI) or UKMA(UK), within the scope of paragraphs (2)(b) and (c) of Article 7 or paragraphs 2(b) and (c) of Article 13d of Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;**]**

(c) the variations do not include—

(i) **[**[F17]a variation of a kind referred to—

(aa) in the case of a UKMA(NI) or UKMA(UK), in paragraph 1 or paragraph 2 of Annex III of Commission Regulation (EC) No 1234/2008;

(bb) in the case of a UKMA(GB), in paragraph 5(3)(a) or (b) of Schedule 10A to the Human Medicines Regulations; or**]**

(ii) a major variation of type II; and

(d) the variations may include one or more minor variations of type IA;

[[F18]"minor variation of type IA"—

(a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(2) of Commission Regulation (EC) No 1234/2008; and

(b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations;**]**

[[F19]"minor variation of type IB"—

(a) in the case of a UKMA(NI) or UKMA(UK), has the meaning given in Article 2(5) of Commission Regulation (EC) No 1234/2008; and

(b) in the case of a UKMA(GB), has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations; and**]**

"work sharing" means **[**[F20], in the case of a UKMA(NI) or UKMA(UK),**]** the work sharing procedure within the meaning of Article 20 of Commission Regulation (EC) No 1234/2008.

F7 Reg. 23(3)(b)(i) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(2) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F8 Words in reg. 23(6) substituted (31.12.2020) by S.I. 2019/775, reg. 1, **Sch. 1 para. 3(3)** (with Sch. 1 para. 11) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 23(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 3(4)(a)(i)** (with Sch. 1 para. 11) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in reg. 23(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 3(4)(a)(ii)** (with Sch. 1 para. 11) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 23(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 3(4)(b)(i)** (with Sch. 1 para. 11) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(b)(ii) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F13 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(c)(i) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F14 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(c)(ii) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F15 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(d) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F16 Words in reg. 23(7) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 3(4)(e)(i)** (with Sch. 1 para. 11) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**); 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(e)(ii) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F18 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(f) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F19 Words in reg. 23(7) substituted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(g) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

F20 Words in reg. 23(7) inserted (31.12.2020) by S.I. 2019/775, Sch. 1 para. 3(4)(h) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(d)**)

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