STATUTORY INSTRUMENTS

2016 No. 190

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

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Medicines (Products for Human Use) (Fees) Regulations 2016 and shall come into force on 1st April 2016.

Interpretation

2. These Regulations shall be interpreted in accordance with Schedule 1.

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.

PART 3

Capital Fees for Applications for Authorisations, Registrations, Licences or Certificates and for Associated Inspections

Fees for applications for authorisations, registrations, licences or certificates etc.

12.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorisation (other than a European Union marketing authorisation), a parallel import licence, a traditional herbal registration, a manufacturer's licence, a manufacturing authorisation, a wholesale dealer's licence, a clinical trial authorisation, a broker's registration or an active substance registration is—

(a) the fee prescribed for that application in Part 2 of Schedule 2; and

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

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

Fee for application to be included on the list of online sellers of medicines

13. The fee payable by an applicant to be included on the list of online sellers of medicines is the fee prescribed for that application in Part 2 of Schedule 2.

Fee for applications for additional copy certificates

14. The fee payable by an applicant for a certified copy of a certificate issued under Article 111(5) of the 2001 Directive is £68.

Fees for applications for certificates and copy certificates by exporters of medicinal products

15.—(1) The fee payable by an applicant for a certificate issued under regulation 31 (certification of manufacturer's licence) of the Human Medicines Regulations, is—

(a) £152, if the applicant requests the certificate to be issued within 24 hours of receipt of the application; and

(b) £68 in any other case.

(2) The fee in paragraph (1)(a) and (b) is for three identical signed certificates.

(3) The fee payable by the applicant for a certified copy of the certificate referred to in paragraph (1) is £34.

PART 4

Capital Fees for Assistance in Obtaining Marketing Authorisations in Other EEA States

Meaning of "set of applications"

16. For the purposes of this Part, a "set of applications" means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorisation in other EEA

States, but only if all the applications relate to applications for marketing authorisations in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or

(b) a number of applications to competent authorities of other EEA States for marketing authorisations relating to a single United Kingdom marketing authorisation, but only if all the applications have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive.

Fees for applications for regulatory assistance under the mutual recognition procedure

17. The fee payable by an applicant to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorisation in another EEA State or in other EEA States, is the fee prescribed in Part 3 of Schedule 2 in connection with the application or set of applications.

Time for payment of fees under regulation 17

18. Unless regulation 51 (applications made by small companies) applies, all sums payable by way of fees under regulation 17 must have been paid at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under the second sub-paragraph of Article 28(1) of the 2001 Directive for an assessment report to be prepared or updated.

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);

[F6(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 F7 for the variation of a manufacturing authorisation.

[F8(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.

[[F9](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.**]**

Textual Amendments

F6 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)

F7 Regulation 44 has been amended by S.I. 2006/1928 and S.I. 2013/532.

F8 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)**)

F9 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)

[[F10]**Fees 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.

Textual Amendments

F10 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.

Textual Amendments

F10 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.

Textual Amendments

F10 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.

Textual Amendments

F10 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.

Textual Amendments

F10 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.

Textual Amendments

F10 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.**]**

Textual Amendments

F10 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 [F11] 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.

Textual Amendments

F11 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—

[F12(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.

[F13(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) **[**F14subject 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) **[**F15of 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) **[**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 a variation of—

(i) **[**F17of 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) **[**F18subject 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) **[**F19the 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;

[F20"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) **[**F21subject 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) **[**F22a 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;

[F23"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;**]**

[[F24]"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 **[**[F25], 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.

Textual Amendments

F12 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)**)

F13 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)**

F14 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)

F15 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)

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)(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)

F17 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)**)

F18 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)**)

F19 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)**)

F20 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)**)

F21 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)

F22 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)**)

F23 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)**)

F24 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)**)

F25 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)**)

PART 6

Capital Fees for Assessment of Labels and Leaflets

Meaning of "set of proposed changes"

24. For the purposes of this Part and Part 5 of Schedule 2, a "set of proposed changes" means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

(a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and

(b) those changes are submitted to the licensing authority at the same time.

Fees for assessment of a set of proposed changes to labels and leaflets

25.—(1) Unless paragraph (2) applies, where—

(a) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a United Kingdom marketing authorisation (other than a parallel import licence) is submitted to the licensing authority in accordance with Article 61(3) of the 2001 Directive; or

(b) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a parallel import licence is submitted to the licensing authority,

the fee payable by the holder of that authorisation or licence is the fee prescribed in Part 5 of Schedule 2 in connection with that change.

(2) Paragraph (1) does not apply where a change to the labelling or package leaflet of a medicinal product is proposed in connection with an application for the variation of the marketing authorisation for that product.

Time for payment of fees under regulation 25

26. All sums payable by way of fees under regulation 25(1) must be paid by the time that the proposed changes are submitted to the licensing authority.

PART 7

Capital Fees for Applications for Renewals of Certain Licences, Authorisations and Registrations and for Associated Inspections

Fees for renewals of certain manufacturer's licences

27.—(1) The fee payable by the applicant for an application to renew a manufacturer's licence which falls within the description in paragraph (2) is £178.

(2) The licence referred to in paragraph (1) is one—

(a) which is solely for the manufacture of medicinal products the sale or supply of which does not require a marketing authorisation or a product licence; and

(b) to which regulation 169 (mixing of general sale medicinal products) of the Human Medicines Regulations applies.

(3) Where an inspection of a site is made in connection with the application referred to in paragraph (1) an inspection fee of £295 is also payable by the applicant.

[F26Fee for renewals of a marketing authorisation

27A. Where an application is made to the licensing authority for the renewal of a marketing authorisation in the case of a product for sale or supply in Great Britain and the application for renewal—

(a) relates to a medicinal product which, at the time the marketing authorisation was granted, contained a new active ingredient; and

(b) is the first renewal in relation to that product,

the fee payable by the applicant is the fee prescribed in Part 6 of Schedule 2.**]**

Textual Amendments

F26 Reg. 27A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 4** (with Sch. 1 para. 11) (as amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 188(e)**); 2020 c. 1, Sch. 5 para. 1(1)

Fees for renewals in terms which are not identical to the existing authorisation, licence or registration

28. Where an applicant applies for renewal of a—

(a) marketing authorisation (other than a European Union marketing authorisation);

(b) traditional herbal registration, or

(c) manufacturer's licence,

so as to contain provisions which are not identical to those in the authorisation, registration or licence as in force at the date of the application, the fee payable under this Part is increased by an amount equal to the fee which would have been payable under Part 5 of these Regulations had the applicant made a separate application for variation of that authorisation, registration or licence in respect of each provision which is not identical.

F27PART 8

Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorisations

. . . . . .

Textual Amendments

F27 Pt. 8 omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 1 para. 5** (with Sch. 1 para. 11); 2020 c. 1, Sch. 5 para. 1(1)

PART 9

Capital Fees for Inspections

Fees for inspections

30.—(1) Unless regulation 31 or Part 16 of these Regulations applies, a fee is payable in accordance with—

(a) paragraphs 1 to 9 of Schedule 3 for inspection of any site made in connection with an application for, or during the currency of, a marketing authorisation, a traditional herbal registration, a clinical trial authorisation, a manufacturing authorisation, a manufacturer's licence a wholesale dealer's licence, a broker's registration or an active substance registration except for an inspection for which a fee is payable under regulation 27 or 34;

(b) paragraph 10 of Schedule 3 for any inspection comprising an office-based evaluation and risk assessment of documentation but not involving inspection of a site, in connection with the monitoring of—

(i) good manufacturing practice;

(ii) good clinical practice;

(iii) good pharmacovigilance practice; or

(iv) good distribution practice.

(2) Unless regulation 32 or 33 applies, the fee in paragraph (1) is payable by the holder of, or as the case may be, applicant for, the authorisation, registration or licence in relation to which the inspection is made.

Fees for inspections of pharmacovigilance service providers

31.—(1) Where an inspection is made of a pharmacovigilance service provider and that inspection is not related to anything done under regulation 30(1)(a), a fee is payable in accordance with paragraphs 1 and 2 of Schedule 3.

(2) The fee in paragraph (1) is payable by the pharmacovigilance service provider who is the subject of an inspection.

(3) In this regulation a "pharmacovigilance service provider" means a provider of pharmacovigilance services to a marketing authorisation holder.

Payer of inspection fee (contract laboratories and API manufacturing sites)

32. Where an inspection is made of a contract laboratory or a site used by an API manufacturer the fee is payable by the operator of that laboratory, or as the case may be, that API manufacturer.

Inspections in connection with multiple applications

33.—(1) Unless paragraph (4) applies, where an inspection is made outside the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

(a) in more than one marketing authorisation, clinical trial authorisation, traditional herbal registration; or

(b) by more than one applicant for such an authorisation, registration or licence,

the fee for the inspection referred to in regulation 30(1) is payable in equal proportions by the holders of, or as the case may be, applicants for, the authorisation, registration or licence.

(2) In paragraph (1), the reference to an applicant for a clinical trial authorisation is a reference to a person who sends a valid notice of amendment as mentioned in regulation 20(1).

(3) Where an inspection is made in the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

(a) in more than one manufacturer's licence or manufacturing authorisation; or

(b) by more than one applicant for such a licence or authorisation,

the fee for the inspection referred to in regulation 30(1) is payable in equal proportions by each applicant.

(4) This regulation does not apply if the inspection is made of a contract laboratory or a site used by an API manufacturer.

Fees for inspections relating to good clinical practice in clinical trials

34. A fee in accordance with paragraph 2 of Schedule 3 is payable by a person in respect of an inspection of one or more sites for the purpose of ascertaining whether that person—

(a) is—

(i) conducting, or has conducted, a clinical trial, or

(ii) performing, or has performed, the functions of a sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),

in accordance with good clinical practice, under regulation 28(1) (good clinical practice and protection of clinical trial subjects) of the Clinical Trials Regulations; or

(b) has put and kept in place arrangements for the purpose of ensuring that with regard to a clinical trial the requirements of good clinical practice are satisfied or adhered to, under regulation 28(2) of those Regulations.

Amount, and time for payment, of inspection fees in respect of an application for a wholesale dealer's licence

35.—(1) All sums payable by way of fees in respect of any inspection of a site in connection with an application for a wholesale dealer's licence under regulation 30(1) must be paid—

(a) in advance of an application; or

(b) at the time that application is made.

(2) Except where paragraph (3) applies, the inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 5(a) of Schedule 3.

(3) The inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 7(3) of Schedule 3 where—

(a) the site to be inspected falls within the description specified in paragraph 7(1)(a) or (b) of Schedule 3; or

(b) the total turnover in respect of sales by way of wholesale dealing in authorised medicinal products of the wholesale dealer does not exceed £35,000 (within the meaning given in paragraph 7(2) of that Schedule)**.**

Adjustment and refund of inspection fees in respect of a wholesale dealer's licence

36.—(1) If the inspection in respect of an application for a wholesale dealer's licence takes longer than the standard period, a further fee of the amount specified in paragraph 5(b) of Schedule 3 is payable by the applicant for each subsequent period of 3 hours and 30 minutes or less.

(2) The fee payable under paragraph (1) 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.

(3) The licensing authority shall refund the whole of the inspection fee paid where, after an inspection fee is paid as a consequence of regulation 35, the application for a wholesale dealer's licence is withdrawn—

(a) before a date on which the inspection is due to take place is arranged with or notified to the applicant; or

(b) in the case where a date on which the inspection is due to take place is fixed, 15 or more days before the date on which that inspection is due to take place.

(4) In this regulation "standard period" means—

(a) in the case where regulation 35(2) applies, a period of more than 7 hours; or

(b) in the case where regulation 35(3) applies, a period of more than 3 hours and 30 minutes.

Amount, and time for payment, of inspection fees in respect of an application for a broker's registration or an active substance registration

37.—(1) All sums payable by way of fees in respect of any assessment or inspection of a site in connection with an application for a broker's registration or an active substance registration under regulation 30(1) must be paid in advance of an application or at the time the application is made.

(2) The inspection fee payable as a consequence of paragraph (1) shall be—

(a) in relation to broker's registrations, the amount specified in paragraph 8(1) of Schedule 3;

(b) in relation to active substance registrations, the amount specified in paragraph 9(1) of Schedule 3.

PART 10

Periodic Fees for Authorisations, Registrations and Licences

Periodic fees

38.—(1) Unless paragraph (4), (5), (6) or (7) or Part 16 of, or Part 4 of Schedule 4 to, these Regulations applies, the periodic fee must be paid for each fee period during which the authorisation, registration or licence is in force, even if it is in force for only part of that fee period.

(2) For the purposes of paragraph (1), marketing authorisations of a type referred to in Part 3 of Schedule 4 shall be treated as if they were one marketing authorisation and only one periodic fee in respect of each relevant fee period is payable in connection with the holding of such authorisations.

(3) The periodic fee is the appropriate fee prescribed in Part 3 of Schedule 4 and, for the purposes of that Part, Parts 1 and 2 of that Schedule have effect.

(4) No periodic fee is payable in respect of the fee period during which a marketing authorisation or a traditional herbal registration is first granted unless the authorisation or registration is granted because of—

(a) a change of ownership application; or

(b) an application for a marketing authorisation or traditional herbal registration which—

(i) is for a product for which an authorisation or registration has expired;

(ii) will contain identical provisions to those contained in the expired authorisation or registration;

(iii) is made by the person who held the expired authorisation or registration; and

(iv) is made no later than three months after the expiry of the authorisation or registration referred to in paragraph (i),

and, in each case, a periodic fee has not been paid in respect of that fee period in connection with the expired marketing authorisation or a traditional herbal registration.

(5) An authorisation, registration or licence which is in force is treated for the purposes of this regulation as not being in force during any part of a fee period if—

(a) at least three months before the commencement of that fee period, the holder of that authorisation, registration or licence has given written notice to the licensing authority indicating that he wishes it to cease to have effect before the commencement of that period; and

(b) no products are sold, supplied or manufactured under that authorisation, registration or licence within that fee period.

(6) No periodic fee is payable in respect of the fee period during which a manufacturing authorisation, a manufacturer's licence or wholesale dealer's licence is first granted unless—

(a) that authorisation or licence is granted because of a change of ownership application; and

(b) a periodic fee has not been paid in respect of that fee period in connection with the manufacturing authorisation or manufacturer's licence or wholesale dealer's licence which is mentioned in that application in the statement of intention to cease activities.

(7) No periodic fee is payable in respect of a clinical trial authorisation, broker's registration or active substance registration.

Periodic fee for persons included on the list of online sellers of medicines

39.—(1) Unless paragraph (3) or (4) applies, the periodic fee must be paid for each fee period during which a person is included on the list of online sellers of medicines, even if the person is included on the list for only part of that fee period.

(2) The periodic fee is the appropriate fee prescribed in Part 3 of Schedule 4.

(3) A person included on the list of online sellers of medicines is treated for the purposes of this regulation as not being included on the list during any part of a fee period if—

(a) at least three months before the commencement of that fee period, the person included on the list of online sellers of medicines has given written notice to the licensing authority indicating that the person wishes to be removed from the list before the commencement of that period; and

(b) no products are sold or supplied, or offered for sale or supply, under that listing within that fee period.

(4) No periodic fee is payable in respect of a fee period if the person is not included on the list of online sellers of medicines on the first day of that fee period.

PART 11

Capital Fees for Application for Membership of Good Clinical Practice Accreditation Scheme and for Certificate of Membership

Meaning of "good clinical practice accreditation scheme"

40. In this Part—

"good clinical practice accreditation scheme" means the non-statutory voluntary scheme of accreditation operated by the licensing authority in relation to Phase 1 trials which participants may join following satisfactory completion of a good clinical practice inspection; and

"Phase 1 trials" are clinical trials to study the pharmacology of a medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.

Fees for applications for membership and certificates

41.—(1) The fee payable by an applicant for membership of the good clinical practice accreditation scheme is £117.

(2) The fee payable by an applicant for a certificate of membership of the good clinical practice accreditation scheme is £62.

PART 12

Capital Fee for a Review Upon Oral Representations or a Person Appointed Hearing

Fee for a review upon oral representations or a person appointed hearing

42.—(1) A fee of £10,000 is payable by a person who gives notice, under any of the provisions specified in paragraph (2), of their wish to—

(a) make further representations to the licensing authority or appear before or be heard by a person appointed, or

(b) propose that there should be a review upon oral representations.

(2) The specified provisions are—

(a) in the Human Medicines Regulations—

(i) regulation 27(3)(b) (procedure where licensing authority propose to suspend, revoke or vary licence);

(ii) regulation 45H(5)(b) [F28] (procedure where licensing authority proposes to suspend or vary a broker's registration to remove a broker from the register);

(iii) regulation 45R(5)(b) [F29] (procedure where licensing authority proposes to suspend or vary an active substance registration or remove the holder of an active substance registration from the register);

(iv) regulation 256J(4)(b) [F30] (procedure where the competent authority of a member State proposes to suspend, vary or remove a person's entry on the list);

(v) paragraphs 11(1), 13(1)(a), 23(2) and 30(2) of Schedule 11 (advice and representations);

(vi) paragraph 3(8) of Schedule 32 (transitional provisions and savings in relation to product licences of right);

(b) in the Clinical Trials Regulations—

(i) paragraph 3(1)(a) of Schedule 5 [F31] (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials);

(ii) paragraph 4(1)(a) of Schedule 8 [F32] (procedural provisions relating proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations).

(3) The licensing authority will refund to that person—

(a) 60% of that fee if the person withdraws the notice two weeks before the commencement of the hearing before the person appointed or the review upon oral representations;

(b) 100% of that fee if, in respect of the hearing before the person appointed or the review upon oral representations, the decision notified by the licensing authority is—

(i) not to revoke, vary, suspend or terminate, as the case may be, the authorisation, licence or certificate of registration;

(ii) not to suspend, vary or remove, as the case may be, a person's entry on the list of online sellers of medicines; or

(iii) to grant or renew, as the case may be, the authorisation, licence or certificate of registration.

Textual Amendments

F28 Regulation 45H was inserted by S.I. 2013/1855.

F29 Regulation 45R was inserted by S.I. 2013/1855.

F30 Regulation 256J was inserted by S.I.2013/1855.

F31 Schedule 5 was substituted by regulation 4 of, and paragraph 5 of Schedule 3 to, S.I. 2005/2754.

F32 Paragraph 4 of Schedule 8 was substituted by regulation 4 of, and paragraph 6 of Schedule 3 to, S.I. 2005/2754.

Time for payment under regulation 42

43. The fee prescribed in regulation 42 is payable at the time the notice is given.

PART 13

Fees in relation to the Part 6 of the Human Medicines Regulations (certification of homoeopathic medicinal products)

Interpretation

44.—(1) In this Part—

"administrative variation" means a variation of the provisions of a certificate of registration which does not require, in the opinion of the licensing authority, medical, scientific or pharmaceutical assessment;

"application" means an application for the grant of a certificate of registration;

"application to the licensing authority for regulatory assistance" in relation to a single certificate of registration means—

(a) a single application of that type; or

(b) a set of applications of that type;

"application for an EC registration in a concerned member State" in relation to a single certificate of registration means—

(a) a single application of that type; or

(b) a set of applications of that type in a number of concerned member States;

"decentralised procedure application" means an application relating to a homoeopathic medicinal product in respect of which at the time of the application—

(a) an EC registration has been granted in an EEA State; and

(b) an application for an EC registration has been made in more than one EEA State under Article 28(1) and (3) [F33] of the 2001 Directive;

"EC registration" means a registration granted by a competent authority of an EEA State in accordance with the procedure set out in Article 14 of the 2001 Directive;

"formulation" does not include the formulation of homoeopathic stock;

"identical" means—

(a) in relation to the formulation of the product, identical as regards the requirements in respect of composition, preparation and testing; and

(b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the test which it is required to undergo;

"mutual recognition procedure incoming application" means an application relating to a homoeopathic medicinal product in respect of which—

(a) an EC registration has already been granted in another EEA State; and

(b) recognition of that certificate is sought from the licensing authority by way of the grant of a certificate of registration in the United Kingdom, under the procedure in Articles 28 and 29(1) to (3) [F34] of the 2001 Directive;

"product" includes a series of products each of which is prepared from identical homoeopathic stocks;

"set of applications" means—

(a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in other EEA States, where those applications to the licensing authority all relate to applications for EC certificates of registration in other EEA States that have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; or

(b) a number of applications to competent authorities of other EEA States for EC certificates of registration relating to a single certificate of registration, where those applications all have the same 90 day assessment period for the purposes of Article 28(4) of the 2001 Directive; and

"standard variation" means a variation of the provisions of a certificate of registration which, in the opinion of the licensing authority, requires medical, scientific or pharmaceutical assessment and which requires in respect of any homoeopathic medicinal products to which that certificate relates—

(a) the replacement of an excipient used in the manufacture of the product with a comparable excipient;

(b) the replacement of a reagent indirectly associated with the manufacturing process of the product or which disappears from that process with a comparable reagent;

(c) a change to the qualitative composition of the container or other form of packaging immediately in contact with the product;

(d) a minor change to the method of manufacture of a homoeopathic stock included in the product;

(e) a change to the specification of any reagent or excipient used in the manufacture of the product;

(f) a change to the finished product specification of the product;

(g) a change to the test procedure for any raw material used in the manufacture of the product;

(h) a change to the test procedure of the product;

(i) a change to the test procedure for the container or other form of packaging immediately in contact with the product;

(j) a change to comply with a supplement to the European Pharmacopoeia or any national pharmacopoeia of a member State;

(k) a change to the shape of the container in which the product may be placed on the market;

(l) an additional pack size in which the product may be placed on the market;

(m) a change to the approved storage conditions for the product;

(n) a change to the shelf life of an unopened container of the product or to the shelf life of the product after the container has been opened for the first time;

(o) a change to the dimensions of an approved dosage form of the product (for example, tablets) which does not entail a change to the quantitative composition or the mean mass of the product; or

(p) a change following modification to the manufacturing authorisation.

(2) In this Part—

(a) any expression used in this Part which is defined in the Human Medicines Regulations shall have the same meaning which it has in those Regulations;

(b) any expressions which are also used in the 2001 Directive shall have the same meaning as they have in the 2001 Directive and related expressions shall be interpreted accordingly;

(c) any reference to doing anything in accordance with a certificate of registration shall be interpreted in accordance with regulation 8(1) of the Human Medicines Regulations (general interpretation); and

(d) any reference to the holder of a certificate of registration shall be interpreted as a reference to the holder of such a certificate which is for the time being in force.

Textual Amendments

F33 Article 28 has been substituted by Article 1(26) of Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34).

F34 Article 29 has been substituted by article 1(26) of Directive 2004/27/EC of the European Parliament and of the Council (OJ No L 136, 30.4.2004, p34).

Fees for applications made at the invitation of the licensing authority

45. No fee shall be payable under this Part in connection with an application for the grant or variation of a certificate of registration under Part 6 (certification of homoeopathic medicinal products) of the Human Medicines Regulations where the application is made at the specific request of the licensing authority.

Fees for applications for certificates

46.—(1) The fee payable by a person who makes an application for the grant of a certificate of registration under regulation 103 (application for certificate of registration) of the Human Medicines Regulations shall be the fee specified in the Table in Schedule 5 to these Regulations according to the type of application.

(2) The fee payable by a person who makes an application or set of applications to the licensing authority for regulatory assistance in connection with obtaining recognition in accordance with the procedure laid down in Articles 28 and 29(1) to (3) of the 2001 Directive of a single certificate of registration in another EEA State, shall be the fee specified in item 4 of the Table in Schedule 5 to these Regulations.

Fees for variations of certificates

47.—(1) The fee payable by an applicant in connection with an application for an administrative variation of a certificate of registration shall be—

(a) where more than one application for an administrative variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £123, and

(ii) in respect of each other application so considered, a fee of £62;

(b) in any other case, a fee of £123.

(2) The fee payable by an applicant in connection with an application for a standard variation of a certificate of registration shall be—

(a) where more than one application for a standard variation is made at the same time by the same applicant and the applications are for identical variations—

(i) in respect of the first application considered by the licensing authority, a fee of £243;

(ii) in respect of each other application so considered, where further medical, technical or scientific assessment is required, a fee of £243;

(iii) in respect of the second to thirtieth applications so considered, where no further medical, technical or scientific assessment is required, a fee of £123;

(iv) in respect of each other application so considered, where no further medical, technical or scientific assessment is required, a fee of £62;

(b) in any other case, a fee of £243.

Time for payment of fees

48.—(1) Any fee payable under regulation 46(1) or 47 shall be payable to the licensing authority—

(a) in advance of the application; or

(b) at the time the application for grant or variation of the certificate of registration is made.

(2) Any fee payable under regulation 46(2) shall be payable to the licensing authority—

(a) in advance of any request; or

(b) at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under Article 28(2) of the 2001 Directive for an assessment report to be prepared or updated.

PART 14

Administration

Payment of fees to Ministers

49. Any sum payable under these Regulations must be paid to one of the Ministers.

Time for payment of capital fees in connection with applications or inspections

50.—(1) All capital fees under these Regulations shall be payable in accordance with—

(a) the specified provisions in paragraph (2) where appropriate, and

(b) paragraph (3).

(2) The specified provisions are—

(a) regulation 11 (time for payment of fees under regulations 4 to 10);

(b) regulation 17 (regulatory assistance);

(c) regulation 25 (change to labels and leaflets);

(d) regulation 35 (inspections in respect of wholesale dealer's licence);

(e) regulation 37 (inspections in respect of brokers and active substance registrations);

(f) regulation 42 (fee for a review upon oral representations or a person appointed hearing); and

(g) regulation 51 (small companies).

(3) All fees payable under this regulation—

(a) in respect of inspections made either in connection with an application for, or during the currency of, an authorisation, licence or certificate 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;

(b) in respect of any other application, must have been paid at the time of the application or before.

Time for payment of capital fees – applications made by small companies

51.—(1) Schedule 6 shall have effect with respect to the capital fee payable in connection with an application made by or on behalf of a small company.

(2) For the purpose of these Regulations, a company is a small company if, for the financial year before that in which the application is made, the total value of products it has sold or supplied for the financial year is not more than the amount for the time being specified in item 1 in

section 382(3) (qualification of company as small) of the Companies Act 2006 [F35] and the conditions in paragraph (3) are met.

(3) The conditions for the purposes of paragraph (2) are—

(a) the company's balance sheet total as defined in section 382(5) of the Companies Act 2006 is not more than the amount for the time being specified in item 2 in section 382(3) of that Act; or

(b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the number for the time being specified in item 3 in section 382(3) of that Act.

Textual Amendments

F35 2006 c.46. A relevant amendment was made by S.I. 2015/980.

Payment of fees in respect of a traditional herbal registration

52.—(1) The fee payable under regulation 12 shall be refunded or, if it has not been paid, shall be waived where an application is made for the grant of a traditional herbal registration—

(a) in accordance with regulation 127 (application for the grant of a traditional herbal registration) of the Human Medicines Regulations;

(b) on the grounds specified in paragraph (2); and

(c) in respect of a medicinal product which falls within the description in paragraph (3).

(2) For the purposes of paragraph (1), the specified grounds are—

(a) that the marketing authorisation in respect of the medicinal product in question; or

(b) in the case of a corresponding product the marketing authorisation relating to product Y (as defined in paragraph (4)),

is to be revoked.

(3) A medicinal product falls within this paragraph if—

(a) a marketing authorisation held by the applicant was granted under Part 5 of the Human Medicines Regulations in respect of that medicinal product; or

(b) that medicinal product is a corresponding product.

(4) For the purposes of paragraph (3), a corresponding product is a product which is characterised by having—

(a) the same active ingredients, irrespective of the excipients used or reduction in the number or quantity of active ingredients;

(b) the same or similar intended purpose, equivalent strength and posology; and

(c) the same or similar route of administration,

as a medicinal product ("product Y") in respect of which a marketing authorisation held by the applicant was granted under Part 5 of the Human Medicines Regulations.

(5) Where the licensing authority determines that the marketing authorisations in respect of the medicinal product in question or the marketing authorisation in respect of product Y should not be revoked, the fee payable under regulation 12 which has been refunded or waived shall become payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

Time for payment of periodic fees

53. All periodic fees must be paid by the first day of the fee period to which they relate, unless otherwise specified in these Regulations.

Penalty fees for late payment of periodic fees

54.—(1) Subject to paragraph (2), if a person has failed to pay a periodic fee by the time it has become payable under regulation 53, a penalty fee is payable by that person.

(2) A penalty fee is payable only if, after a period of 60 days commencing on the date of the written notice ("the notice") issued by the licensing authority requiring payment of that fee, the fee remains unpaid.

(3) Unless regulation 55 applies, where a periodic fee remains unpaid after 60 days commencing on the date of the notice, the penalty fee is—

(a) £100 where the total unpaid fee exceeds £200; or

(b) £50 where the total unpaid fee does not exceed £200.

(4) In paragraph (3), the "total unpaid fee" means the total of all the periodic fees payable by a person in connection with all the authorisations, registrations or licences held by that person.

Daily penalty fees for late payment of periodic fees

55. If the periodic fee and penalty fee under regulation 54 ("the outstanding amount") have not been paid within a period of 90 days commencing on the date of the written notice issued by the licensing authority, the amount of penalty fee payable shall be the amount specified in regulation 54 (3) plus £5 for each day of the period which—

(a) begins with the day 90 days from the date of the written notice; and

(b) ends with the day before that on which payment of the outstanding amount is actually made.

Refund or waiver of fees under regulation 54 or 55

56. The licensing authority may refund or waive payment of the penalty fee, or reduce the amount payable, where it is satisfied that the holder of the authorisation, registration or licence was not responsible for the failure to pay the periodic fee within the period specified in regulation 54(2) or 55.

Adjustment, waiver, reduction or refund of fees

57.—(1) If after a capital or periodic fee is paid it becomes apparent that—

(a) a lesser fee should have been paid, the excess shall be refunded to the applicant or, as the case may be, the holder of the authorisation, registration or licence concerned; or

(b) a higher fee should have been paid, the balance due shall be payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority to the applicant or, as the case may be, the holder of the authorisation, registration or licence concerned requiring payment of that balance.

(2) The licensing authority shall, to the extent provided in Schedule 7 in relation to capital fees or in Schedule 8 in relation to periodic fees—

(a) adjust, waive payment of or reduce any fee or part of a fee otherwise payable under these Regulations; or

(b) refund the whole or part of any fee already paid.

Suspension of licences and authorisations

58.—(1) Where any sum due by way of, or on account of, any fee or any part of a fee payable under these Regulations remains unpaid by—

(a) the holder of a product licence or a product licence of right;

(b) the holder of a manufacturer's licence;

(c) the holder of a manufacturer's authorisation;

(d) the holder of a wholesale dealer's licence; or

(e) a person included on the list of online sellers of medicines,

the licensing authority may serve a written notice on the holder requiring payment of the sum unpaid.

(2) If after a period of one month commencing on the date of service of the notice referred to in paragraph (1), or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence, authorisation or entry on the list of online sellers of medicines, as the case may be, until such sum has been paid.

Civil proceedings to recover unpaid fees

59. All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.

PART 15

Amendments to Other Legislation

Amendment of the Medical Devices (Consultation Requirements) (Fees) Regulations 1995

60.—(1) The Medical Devices (Consultation Requirements) (Fees) Regulations 1995 [F36] are amended as follows.

(2) In regulation 3 (fees)—

(a) in paragraph (1)—

(i) in sub-paragraph (a), for "£4,595" substitute " £4,136 ", and

(ii) in sub-paragraph (b), for "£10,711" substitute " £9,640 ";

(b) in paragraph (2)—

(i) in sub-paragraph (a), for "£909" substitute " £818 ", and

(ii) in sub-paragraph (b), for "£2,542" substitute " £2,288 ";

(c) in paragraph (3)—

(i) in sub-paragraph (a), for "£4,595" substitute " £4,136 ", and

(ii) in sub-paragraph (b), for "£10,711" substitute " £9,640 ";

(d) in paragraph (4)—

(i) in sub-paragraph (a), for "£909" substitute " £818 ", and

(ii) in sub-paragraph (b), for "£2,542" substitute " £2,228 "; and

(e) in paragraph (5)—

(i) in sub-paragraph (a), for "£46,996" substitute " £42,296 ", and

(ii) in sub-paragraph (b), for "£11,668" substitute " £10,501 ".

(3) In paragraph (2) of regulation 3A (fees for pre-consultation meetings)—

(a) in sub-paragraph (a), for "£832" substitute " £749 ";

(b) in sub-paragraph (b), for "£1,054" substitute " £949 ";

(c) in sub-paragraph (c), for "£1,443" substitute " £1,299 "; and

(d) in sub-paragraph (d), for "£1,831" substitute " £1,648 ".

Textual Amendments

F36 S.I. 1995/449; relevant amendments are made by S.I. 2007/803, 2008/530 and 2010/557.

Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004

61.—(1) The Medicines for Human Use (Clinical Trials) Regulations 2004 [F37] are amended as follows.

(2) In regulations—

(a) 17(2)(b)(ii) (request for authorisation to conduct a clinical trial);

(b) 24(10) (amendments by the sponsor);

(c) 38(3)(b) (application for manufacturing authorisation); and

(d) 44(8) (variation of manufacturing authorisation)

for "Medicines (Products for Human Use) (Fees) Regulations 2013" substitute " Medicines (Products for Human Use) (Fees) Regulations 2016 ".

Textual Amendments

F37 S.I. 2004/1031; relevant amendments are made by S.I. 2006/1928 and 2013/532.

Amendment of the Human Medicines Regulations 2012

62. In regulation 8(1) [F38] of the Human Medicines Regulations (general interpretation), in the definition of "Fees Regulations" for "the Medicines (Products for Human Use) (Fees) Regulations 2013" substitute " the Medicines (Products for Human Use) (Fees) Regulations 2016 ".

Textual Amendments

F38 Regulation 8 was amended by S.I. 2013/1855 and 2593.

PART 16

Revocations and Savings

The Medicines (Products for Human Use) (Fees) Regulations 2013

63.—(1) Subject to paragraphs (2) to (4), the Medicines (Products for Human Use) (Fees) Regulations 2013 [F39] ("the 2013 Regulations") are revoked.

(2) The savings introduced by regulation 59(2) to (4) and 60(2) and (3) of the 2013 Regulations shall continue to apply as if those paragraphs of those regulations had not been revoked.

(3) The 2013 Regulations shall continue to apply as if they had not been revoked in relation to—

(a) capital fees payable under the 2013 Regulations in respect of any application or inspection made before the date on which these Regulations come into force; and

(b) any periodic fee payable under the 2013 Regulations in relation to a fee period ending before the date on which these Regulations come into force.

(4) The revocation of the 2013 Regulations shall not affect any proceedings under those Regulations for the recovery of any fees due as debts to the Crown and for the purposes of those proceedings, the 2013 Regulations shall continue to apply as if they had not been revoked.

Textual Amendments

F39 S.I. 2013/532.

Signed by authority of the Secretary of State for Health.

George Freeman
Parliamentary Under-Secretary of State,
Department of Health

Simon Hamilton
Minister for Health, Social Services and Public Safety

John Penrose
George Hollingbery
Two of the Lords Commissioners of Her Majesty's Treasury

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 :

- Sch. 1 para. 1 words inserted by S.I. 2023/314 reg. 23
- Sch. 2 para. 38 omitted by S.I. 2019/775 Sch. 1 para. 7(9)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(vii))
- Sch. 2 para. 38(4) substituted by S.I. 2019/775 Sch. 1 para. 7(9)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(9) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(vii))
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(i)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(ii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(iii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(iv)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(v)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(a)(vi)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(b)(i)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(b)(ii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(b)(iii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(b)(iv)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(b)(v)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(c)(i)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(c)(ii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(c)(iii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(c)(iv)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(c)(v)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(d)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(e)(i)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(e)(ii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(e)(iii)
- Sch. 2 para. 24(5) sum substituted by S.I. 2023/314 reg. 24(3)(f)
- Sch. 2 para. 25(1)(a) sum substituted by S.I. 2023/314 reg. 24(4)(a)
- Sch. 2 para. 25(1)(b) sum substituted by S.I. 2023/314 reg. 24(4)(b)
- Sch. 2 para. 28(4)(b) sum substituted by S.I. 2023/314 reg. 24(6)(c)
- Sch. 2 para. 30(1)(a) sum substituted by S.I. 2023/314 reg. 24(8)(a)
- Sch. 2 para. 30(1)(b) sum substituted by S.I. 2023/314 reg. 24(8)(b)
- Sch. 2 para. 30(1)(c) sum substituted by S.I. 2023/314 reg. 24(8)(c)
- Sch. 2 para. 31(1) sum substituted by S.I. 2023/314 reg. 24(9)(a)
- Sch. 2 para. 31(2) sum substituted by S.I. 2023/314 reg. 24(9)(b)
- Sch. 2 para. 31(5) sum substituted by S.I. 2023/314 reg. 24(9)(c)
- Sch. 2 para. 32(1) sum substituted by S.I. 2023/314 reg. 24(10)(a)
- Sch. 2 para. 32(2) sum substituted by S.I. 2023/314 reg. 24(10)(b)
- Sch. 2 para. 33(1)(a) sum substituted by S.I. 2023/314 reg. 24(11)(a)(i)
- Sch. 2 para. 33(1)(b) sum substituted by S.I. 2023/314 reg. 24(11)(a)(ii)
- Sch. 2 para. 33(2) sum substituted by S.I. 2023/314 reg. 24(11)(b)
- Sch. 2 para. 34(a) sum substituted by S.I. 2023/314 reg. 24(12)(a)
- Sch. 2 para. 34(b) sum substituted by S.I. 2023/314 reg. 24(12)(b)
- Sch. 2 para. 35(1) sum substituted by S.I. 2023/314 reg. 24(13)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(i)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(ii)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(iii)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(iv)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(v)

- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vi)
- Sch. 2 para. 38 Table 1 sum substituted by S.I. 2023/314 reg. 24(15)(a)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(i)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(ii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(iv)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(v)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vi)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(vii)
- Sch. 2 para. 38 Table 2 sum substituted by S.I. 2023/314 reg. 24(15)(b)(viii)
- Sch. 2 para. 40(1) sum substituted by S.I. 2023/314 reg. 24(16)
- Sch. 2 para. 42(1)(a) sum substituted by S.I. 2023/314 reg. 24(17)(a)
- Sch. 2 para. 42(1)(b) sum substituted by S.I. 2023/314 reg. 24(17)(b)
- Sch. 2 para. 42(1)(c) sum substituted by S.I. 2023/314 reg. 24(17)(c)
- Sch. 2 para. 43(a) sum substituted by S.I. 2023/314 reg. 24(18)(a)
- Sch. 2 para. 43(b) sum substituted by S.I. 2023/314 reg. 24(18)(b)
- Sch. 2 para. 44 sum substituted by S.I. 2023/314 reg. 24(19)
- Sch. 2 para. 45 sum substituted by S.I. 2023/314 reg. 24(20)
- Sch. 2 para. 46 sum substituted by S.I. 2023/314 reg. 24(21)
- Sch. 2 para. 47 sum substituted by S.I. 2023/314 reg. 24(22)
- Sch. 2 para. 48 sum substituted by S.I. 2023/314 reg. 24(23)
- Sch. 2 para. 49(1) sum substituted by S.I. 2023/314 reg. 24(24)
- Sch. 2 para. 53(a)(ii) sum substituted by S.I. 2023/314 reg. 24(25)
- Sch. 2 para. 54(1)(a) sum substituted by S.I. 2023/314 reg. 24(26)(a)(i)
- Sch. 2 para. 54(1)(b) sum substituted by S.I. 2023/314 reg. 24(26)(a)(ii)
- Sch. 2 para. 54(2) sum substituted by S.I. 2023/314 reg. 24(26)(b)
- Sch. 2 para. 56(a) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 56(b) sum substituted by S.I. 2023/314 reg. 24(27)(a)
- Sch. 2 para. 57(2)(a)(i) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(a)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(a)
- Sch. 2 para. 57(2)(b)(i) sum substituted by S.I. 2023/314 reg. 24(28)(b)
- Sch. 2 para. 57(2)(b)(ii) sum substituted by S.I. 2023/314 reg. 24(28)(c)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(a)
- Sch. 2 para. 1 words inserted by S.I. 2023/314 reg. 24(2)(b)
- Sch. 2 para. 4(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(2) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(i))
- Sch. 2 para. 22(1) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(ii)(aa))
- Sch. 2 para. 22(2)(f) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(b) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(ii)(bb))
- Sch. 2 para. 22(3) words substituted by S.I. 2019/775 Sch. 1 para. 7(3)(c) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(3)(c) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(ii)(cc))
- Sch. 2 para. 23(a) words substituted by S.I. 2019/775 Sch. 1 para. 7(4)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 7(4)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(g)(iii)(aa))
- Sch. 3 para. 2(1)(a) sum substituted by S.I. 2023/314 reg. 25(2)(a)
- Sch. 3 para. 2(1)(b) sum substituted by S.I. 2023/314 reg. 25(2)(b)
- Sch. 3 para. 5(a) sum substituted by S.I. 2023/314 reg. 25(3)(a)
- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(a)

- Sch. 3 para. 5(b) sum substituted by S.I. 2023/314 reg. 25(3)(b)
- Sch. 3 para. 6(2)(a) sum substituted by S.I. 2023/314 reg. 25(4)(a)
- Sch. 3 para. 6(2)(b) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 6(2)(c) sum substituted by S.I. 2023/314 reg. 25(4)(b)
- Sch. 3 para. 7(3) sum substituted by S.I. 2023/314 reg. 25(5)
- Sch. 3 para. 8(1)(a) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(i)
- Sch. 3 para. 8(1)(b) sum substituted by S.I. 2023/314 reg. 25(6)(a)(ii)
- Sch. 3 para. 8(3) sum substituted by S.I. 2023/314 reg. 25(6)(b)
- Sch. 3 para. 9(1)(a)(i) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(i)
- Sch. 3 para. 9(1)(a)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(a)(ii)
- Sch. 3 para. 9(1)(b)(i) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(i)
- Sch. 3 para. 9(1)(b)(ii) sum substituted by S.I. 2023/314 reg. 25(7)(b)(ii)
- Sch. 3 para. 9(3)(a) sum substituted by S.I. 2023/314 reg. 25(7)(c)(i)
- Sch. 3 para. 9(3)(b) sum substituted by S.I. 2023/314 reg. 25(7)(c)(ii)
- Sch. 3 para. 10(a) sum substituted by S.I. 2023/314 reg. 25(8)(a)
- Sch. 3 para. 10(b) sum substituted by S.I. 2023/314 reg. 25(8)(b)
- Sch. 4 para. 15(1) substituted by S.I. 2023/314 reg. 26(7)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(a)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(b)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(c)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(d)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(e)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(f)
- Sch. 4 para. 5 sum substituted by S.I. 2023/314 reg. 26(2)(g)
- Sch. 4 para. 6 sum substituted by S.I. 2023/314 reg. 26(3)
- Sch. 4 para. 7(a) sum substituted by S.I. 2023/314 reg. 26(4)(a)
- Sch. 4 para. 7(b) sum substituted by S.I. 2023/314 reg. 26(4)(b)
- Sch. 4 para. 11(1) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 11(2) sum substituted by S.I. 2023/314 reg. 26(5)
- Sch. 4 para. 12(1) sum substituted by S.I. 2023/314 reg. 26(6)(a)
- Sch. 4 para. 12(2) sum substituted by S.I. 2023/314 reg. 26(6)(b)
- Sch. 4 para. 16 sum substituted by S.I. 2023/314 reg. 26(9)
- reg. 4(a) sum substituted by S.I. 2023/314 reg. 3(a)
- reg. 4(b) sum substituted by S.I. 2023/314 reg. 3(b)
- reg. 4(c) sum substituted by S.I. 2023/314 reg. 3(c)
- reg. 4(d) sum substituted by S.I. 2023/314 reg. 3(d)
- reg. 4(e) sum substituted by S.I. 2023/314 reg. 3(e)
- reg. 5(1)(a) sum substituted by S.I. 2023/314 reg. 4(a)
- reg. 5(1)(b) sum substituted by S.I. 2023/314 reg. 4(b)
- reg. 6 sum substituted by S.I. 2023/314 reg. 5
- reg. 7(1)(a) sum substituted by S.I. 2023/314 reg. 6(a)
- reg. 7(1)(b) sum substituted by S.I. 2023/314 reg. 6(b)
- reg. 8 sum substituted by S.I. 2023/314 reg. 7
- reg. 9 sum substituted by S.I. 2023/314 reg. 8
- reg. 10(1) sum substituted by S.I. 2023/314 reg. 9
- reg. 12(1) words inserted by S.I. 2023/314 reg. 10
- reg. 14 sum substituted by S.I. 2023/314 reg. 11
- reg. 15(1)(a) sum substituted by S.I. 2023/314 reg. 12(a)
- reg. 15(1)(b) sum substituted by S.I. 2023/314 reg. 12(b)
- reg. 15(3) sum substituted by S.I. 2023/314 reg. 12(c)
- reg. 21(1) sum substituted by S.I. 2023/314 reg. 18
- reg. 22(1) sum substituted by S.I. 2023/314 reg. 19
- reg. 23(3)(b)(i) substituted by S.I. 2019/775 Sch. 1 para. 3(2) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 3(2)-(4) substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 188(d))

- reg. 27(1) sum substituted by S.I. 2023/314 reg. 20(a)
- reg. 27(3) sum substituted by S.I. 2023/314 reg. 20(b)
- reg. 41(1) sum substituted by S.I. 2023/314 reg. 21(a)
- reg. 41(2) sum substituted by S.I. 2023/314 reg. 21(b)
- reg. 42(1) sum substituted by S.I. 2023/314 reg. 22

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