# SCHEDULES

## SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

## PART 18

### Amendment of Schedule 1 (amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016)

**188.** In Schedule 1 (amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016)—

(a) before paragraph 1 insert—

"**Insertion of new regulation 10A (waiver for advice given to small and medium companies)**

**1ZA.** After regulation 10 insert—

"**Waiver 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(**1**) respectively.".";

(b) in paragraph 1 (amendment of regulation 19 (capital fees for applications for variations of authorisations)), after sub-paragraph (a) insert—

"(aa) after paragraph (1)(d), insert—

"(e) under Commission Regulation (EC) No 1234/2008 for the variation of a UKMA(UK) or UKMA(NI).";";

(c) in paragraph 2 (insertion of regulations 19A–19F (fees for plasma master files, vaccine antigen master files, post-authorisation safety studies, major safety reviews, periodic safety update reports and batch testing))—

(i) in the inserted regulation 19C (fees for assessment of post-authorisation safety studies)—

(aa) for paragraph (2) substitute—

(**1**) 2006 c.46.

"(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.";

(bb) for paragraph (3) substitute—

"(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.";

(ii) in new regulation 19D (fee for carrying out a major safety review), in paragraph (1)—

(aa) before "marketing authorisation" insert "United Kingdom";

(bb) after "a set of" insert "such";

(d) in paragraph 3 (amendment of regulation 23 (applications for multiple variations)), for sub-paragraphs (2) to (4) substitute—

"(2) For paragraph (3)(b)(i) substitute—

"(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".

(3) For paragraph (6) substitute—

"(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.".

(4) In paragraph (7)—

(a) in the definition of "Major Variation (Type II) Group Application"—

(i) for sub-paragraph (b) substitute—

"(b) subject 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;";

(ii) for sub-paragraph (c)(i) substitute—

"(i) of 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;";

(b) in the definition of "Major Variation (Type II) Complex Group Application"—

(i) for sub-paragraph (b) substitute—

"(b) subject 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;";

(ii) for sub-paragraph (c)(i) substitute—

"(i) of 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;";

(c) in the definition of "Major Variation (Type II) Extended Complex Group Application"—

(i) for sub-paragraph (b) substitute—

"(b) subject 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;";

(ii) for sub-paragraph (c) substitute—

"(c) the 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) for the definition of "major variation of type II" substitute—

""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;";

(e) in the definition of "Minor Variation (Type IB) Group Application"—

(i) for sub-paragraph (b) substitute—

"(b) subject 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;";

(ii) for sub-paragraph (c)(i) substitute—

"(i) a variation of a kind referred to—

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

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

(f) for the definition of "minor variation of type IA" substitute—

""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;";

(g) for the definition of "minor variation of type IB" substitute—

""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";

(h) in the definition of "work sharing", after "means" insert ", in the case of a UKMA(NI) or UKMA(UK),".";

(e) in paragraph 4 (insertion of regulation 27A (fee for renewals of a marketing authorisation)), in the inserted regulation 27A, after "renewal of a marketing authorisation" insert "in the case of a product for sale or supply in Great Britain";

(f) in paragraph 6 (amendment of Schedule 1 (general interpretation provisions)), in sub-paragraph (a)—

(i) before paragraph (i) insert—

"(ai) in the definition of "marketing authorisation", in paragraph (a) after "Human Medicines Regulations" insert "(and a reference to a UKMA(GB), UKMA(NI) or UKMA(UK) should be construed in accordance with those Regulations)";";

(ii) in paragraph (iv), after the definition of "the EMA" insert—

""under the unfettered access route" has the meaning given by regulation 8(1) of the Human Medicines Regulations;";

(g) in paragraph 7 (amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates))—

(i) for sub-paragraph (2) substitute—

"(2) For paragraph 4(a) substitute—

"(a) for an extension of a marketing authorisation—

(i) in the case of a UKMA(NI) or UKMA(UK), within the meaning of Article 2(4) of Commission Regulation (EC) No 1234/2008; or

(ii) in the case of a UKMA(GB), within the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations; and".";

(ii) in sub-paragraph (3)—

(aa) in paragraph (a), for "paragraph 1 of Schedule 10A to the Human Medicines Regulations" substitute—

"—

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

(b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(bb) in paragraph (b), for "paragraph 1 of Schedule 10A to the Human Medicines Regulations" substitute—

"—

(i) in the case of a UKMA(NI) or UKMA(UK), Article 2(4) of Commission Regulation (EC) No 1234/2008;

(ii) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(cc) in paragraph (c), for "paragraph 1 of Schedule 10A to the Human Medicines Regulations" substitute—

"—

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

(b) in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(iii) in sub-paragraph (4)—

(aa) in paragraph (a), for "substitute" to the end, "substitute in the case of a UKMA(NI) or UKMA(UK), paragraph 1 (changes to active substances) or paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex I to Commission Regulation (EC) No 1234/2008 applies or, in the case of a UKMA(GB), sub-paragraph (a) (changes to active substances) or sub-paragraph (b) (changes to strength, pharmaceutical form and route of administration) of the definition of "extension of a UK marketing authorisation" in paragraph 1 of Schedule 10A to the Human Medicines Regulations applies";

(bb) in paragraph (b), for "paragraph 1 of Schedule 10A to the Human Medicines Regulations" substitute "in the case of a UKMA(NI) or UKMA(UK), Article 2(3) of Commission Regulation (EC) No 1234/2008 or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(cc) in paragraph (c), for "paragraph 1 of Schedule 10A to the Human Medicines Regulations" substitute "in the case of a UKMA(NI) or UKMA(UK), Commission Regulation (EC) No 1234/2008 or, in the case of a UKMA(GB), paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(iv) in sub-paragraph (5), for the table substituted in paragraph 24, substitute—

"**Fees for marketing authorisation applications**

| *Column 1*<br><br>*Kind of application* | | *Column 2*<br><br>*Fee payable* |
|---|---|---|
| **1. Major Application** | | |
| (a) | in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex 1 to the 2001 Directive applies | £29,732 |
| (b) | which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £62,421 |
| (c) | which is a European reference product application in the case of a product for sale or supply in Northern Ireland | £62,421 |
| (d) | which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for UKMA(GB) | £62,421 |
| (e) | in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 | £18,437 |
| (f) | in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive | £62,421 |
| (g) | in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application) | £18,437 |
| (h) | in any other case | £92,753 |
| **2. Complex application** | | |
| (a) | which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £17,330 |
| (b) | which is a European reference product application in the case of a product for sale or supply in Northern Ireland | £17,330 |
| (c) | which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £17,330 |

| *Column 1* | | *Column 2* |
|---|---|---|
| *Kind of application* | | *Fee payable* |
| (d) | in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 | £10,443 |
| (e) | in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive | £17,330 |
| (f) | in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application) | £10,443 |
| (g) | in any other case | £25,643 |
| **3. Standard application** | | |
| (a) | which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £6,350 |
| (b) | which is a European reference product application in the case of a product for sale or supply in Northern Ireland | £6,350 |
| (c) | which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £6,350 |
| (d) | in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 | £5,783 |
| (e) | in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by competent authorities of the EEA under Article 28 of the 2001 Directive | £6,350 |
| (f) | in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application) | £5,783 |
| (g) | in any other case | £9,402 |
| **4. Simple application** | | |
| (a) | which is a mutual recognition procedure incoming application in the case of a product for sale or supply in Northern Ireland, | £2,564 |

| *Column 1* | | *Column 2* |
|---|---|---|
| *Kind of application* | | *Fee payable* |
| | and the subsequent associated application under the unfettered access route for a UKMA(GB) | |
| (b) | which is a decentralised procedure application in the case of a product for sale or supply in Northern Ireland, and the subsequent associated application under the unfettered access route for a UKMA(GB) | £2,564 |
| (c) | in respect of an application for a UKMA(GB) under the unfettered access route where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 | £2,564 |
| (d) | in respect of an application for a UKMA(GB) or UKMA(UK), other than a UKMA(GB) under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive | £2,564 |
| (e) | in respect of an application for a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application) | £2,564 |
| (f) | in any other case | £2,564 |
| **5. Parallel import licence applications** | | |
| (a) | in respect of a simple parallel import licence | £1,792 |
| (b) | in respect of a standard parallel import licence | £6,663 |
| (c) | in respect of a complex parallel import licence | £18,180 |
| **6. Change of ownership application** | | £442". |

(v) in sub-paragraph (6), in the inserted paragraph 24A—

(aa) in the heading, for "exit day" substitute "IP completion day";

(bb) in sub-paragraph (1), for "exit day" substitute "IP completion day";

(vi) after paragraph (8) insert—

"(8A) After paragraph 28 (application for multiple authorisations) insert—

"**Application by pre-assessment of modules**

**28A.**—(1) Where an applicant for a United Kingdom marketing authorisation submits material in accordance with regulation 50(5) of the Human Medicines Regulations for pre-assessment by the licensing authority rather than as part of the submission of a full application for that marketing authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

(a) £23,188.25 in respect of Module 3 (chemical, pharmaceutical and biological information);

(b) £23,188.25 in respect of Module 4 (non-clinical reports);

(c) £23,188.25 in respect of Module 5 (clinical study reports).

(2) Where an applicant for a United Kingdom marketing authorisation for a similar biological medicinal product submits material in accordance with regulations 53, 53A or 53B of the Human Medicines Regulations for pre-assessment of a complex abridged application by the licensing authority rather than as part of the submission of a full application for that marketing authorisation, the fee payable in respect of pre-assessment of each of the following Modules (as defined in Annex I to the 2001 Directive) is—

(a) £4,332.50 in respect of Module 3 (chemical, pharmaceutical and biological information);

(b) £4,332.50 in respect of Module 4 (non-clinical reports);

(c) £4,332.50 in respect of Module 5 (clinical study reports).

(3) The fee payable under sub-paragraphs (1) and (2) 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 the fee.

(4) Where a fee has been paid under this paragraph, any fee payable under regulation 12(1) in connection with an application for the grant of a United Kingdom marketing authorisation in respect of the same product is reduced by the amount paid under this paragraph provided that no further assessment of the Module concerned is required.”.”;

(vii) for sub-paragraph (9) substitute—

“(9) In paragraph 38—

(a) in sub-paragraph (4)(b), after “Commission Regulation (EC) 1234/2008” insert “and of marketing authorisations in force in Great Britain”;

(b) after sub-paragraph (6)—

(i) for Table 1 substitute—

“**Table 1**

**Fees for applications for variations of marketing authorisations falling within the scope of Chapter II of Commission Regulation (EC) No 1234/2008**

| *Column 1*<br>*Kind of variation* | *Column 2*<br>*Fee payable* |
|---|---|
| **1. Application for a single kind variation** | |
| (a) Type IB Application | £277 |
| (b) Type II Application | £277 |
| (c) Type II Complex Variation Application | £2,493 |
| (d) Extended Type II Complex Variation Application | £7,693 |
| **2. Applications for a Group** | |
| (a) Minor Variation (Type IB) Group Application | £277 |
| (b) Major Variation (Type II) Group Application | £496 |

| *Column 1* *Kind of variation* | | *Column 2* *Fee payable* |
|---|---|---|
| (c) | Major Variation (Type II) Complex Group Application | £2,703 |
| (d) | Major Variation (Type II) Extended Complex Group Application | £7,883”; |

(ii) in Table 2—

(aa) in the heading to the table, after “Commission Regulation (EC) No 1234/2008” insert “and of marketing authorisations in force in Great Britain”;

(bb) after row 8 insert—

| | |
|---|---|
| “**9** Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related UKMA(NI) for the same product | £nil |
| **10** Variation of a UKMA(GB) which was granted following an application made under the unfettered access route, provided a corresponding variation has been approved to the related European Union marketing authorisation for the same product | Apply fees and fee categories in Table 1 |
| **11** Variation of a UKMA(UK) or a UKMA(GB) which was granted following an application other than an application made under the unfettered access route, where the medicinal product concerned has already been granted a marketing authorisation by a competent authority of an EEA State under Article 28 of the 2001 Directive, provided a corresponding variation has been approved to the related marketing authorisation or UKMA(NI) for the same product | Apply fees and fee categories in Table 1 |
| **12** Variation of a UKMA(GB) which was granted following an application where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), provided a corresponding variation has been approved to the related European Union marketing authorisation or UKMA(NI) for the same product | Apply fees and fee categories in table 1”;”; |

(viii) in sub-paragraph (12), in the inserted paragraph 40A—

(aa) in the heading for “exit day” substitute “IP completion day”;

(bb) in subparagraph (1) for “exit day” substitute “IP completion day”;

(ix) in sub-paragraph (13)—

(aa) for the inserted paragraph 56 substitute—

"**56.** Unless paragraph 57 applies, the fee payable under regulation 27A in connection with an application for the renewal of a United Kingdom marketing authorisation is—

(a) in respect of an application for renewal of a UKMA(GB) granted under the unfettered access route, £747;

(b) in respect of an application for renewal of a UKMA(GB) where the medicinal product concerned has already been granted a European Union marketing authorisation under Regulation (EC) No 726/2004 (an automatic recognition application), £747;

(c) in all other cases, £9,682.";

(bb) for the inserted paragraph 57(2) substitute—

"(2) The fee payable under regulation 27A for applications to which sub-paragraph (1) applies is—

(a) in respect of applications for renewal of more than one UKMA(GB) granted under the unfettered access route or UKMA(GB) 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 renewal application has been made to the related European Union marketing authorisation or UKMA(NI) for the same product—

(i) £747 for the first application considered by the licensing authority; and

(ii) £747 for each other application;

(b) in all other cases—

(i) £9,682 for the first application considered by the licensing authority; and

(ii) £747 for each other application.";

(h) after paragraph 8 insert—

"**Amendment of Schedule 6 (time for payment of capital fees: small companies)**

**8A.** In Schedule 6, in paragraph 2, for "entry 1(f)" substitute "entry 1(h)".".

**189.** In Schedule 2 (insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)), in the inserted Schedule 8B—

(a) in the entry in the table for "Part I, paragraph 5.2(a)", in the corresponding modification, for "regulations 51 to 56" substitute "regulations 51A, 52A, 53A and 54 to 56";

(b) in the entry in the table for "Part I, paragraph 5.2.1, second paragraph", in the corresponding modification, for "regulation 51" substitute "regulation 51A";

(c) in the entry in the table for "Part II, paragraph 2(b)", in the corresponding modification, for "regulation 51" substitute "regulation 51A";

(d) in the entry in the table for "Part II, paragraph 4, first paragraph", in the corresponding modification, for "regulation 53" substitute "regulation 53A".