SCHEDULE 1

Regulation 3

Amendment of the Medicines (Products for Human Use) (Fees) Regulations 2016

Amendment of regulation 19 (capital fees for applications for variations of authorisations)

1. In regulation 19—

(a) in paragraph (1)(a), for paragraph (ii) substitute—

"(ii) 65C (variation of a UK marketing authorisation)"; and

(b) after paragraph (3) insert—

"(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.".

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)

2. After regulation 19, insert—

"**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.

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.

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 study protocol for a post-authorisation safety study in accordance with paragraph 29(1)(a) of Schedule 12A to the Human Medicines Regulations is £8,309.

(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 paragraph 29(1)(b) of Schedule 12A to the Human Medicines Regulations is £8,309.

Fee for carrying out a major safety review

19D.—(1) Where the licensing authority conducts a major safety review of a marketing authorisation or traditional herbal registration, or a set of 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.

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.

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.

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.".

Amendment of regulation 23 (applications for multiple variations)

3.—(1) Regulation 23 is amended as follows.

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

"(i) have agreed 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) In paragraph (6), for "Article 5 of Commission Regulation (EC) No 1234/2008" substitute "paragraph 3 of Schedule 10A to the Human Medicines Regulations".

(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 within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;", and

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

"(i) of a kind referred to 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 within the scope of paragraphs 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;", and

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

"(i) of a kind referred to in paragraph 5(3)(a) or (c) of Schedule 10A to the Human Medicines Regulations; or";

(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 within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;", and

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

"(c) the variations do not include a variation of a kind referred to in paragraph 5(3)(a) of Schedule 10A to the Human Medicines Regulations; and";

(d) in the definition of "major variation of type II", for "Article 2(3) of Commission Regulation (EC) No 1234/2008" substitute "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 within the scope of paragraph 5(2)(b) or (c) of Schedule 10A to the Human Medicines Regulations;", and

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

"(i) a variation of a kind referred to in paragraph 5(3)(a) or (b) of Schedule 10A to the Human Medicines Regulations; or";

(f) in the definition of "minor variation of type IA", for "Article 2(2) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(g) in the definition of "minor variation of type IB", for "Article 2(5) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations"; and

(h) omit the definition of "work sharing".

Insertion of regulation 27A (fee for renewals of a marketing authorisation)

4. After regulation 27, insert—

"**Fee for renewals of a marketing authorisation**

27A. Where an application is made to the licensing authority for the renewal of a marketing authorisation 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.".

Omission of Part 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)

5. Omit Part 8.

Amendment of Schedule 1 (general interpretation provisions)

6. In Schedule 1—

(a) in paragraph 1—

(i) in the definition of "medicinal product", for "includes any medicinal product for human use to which the 2001 Directive applies and" substitute "has the meaning given by regulation 2 of the Human Medicines Regulations and includes",

(ii) for the definition of "orphan medicinal product" substitute—

""orphan marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations;",

(iii) in the definition of "variation", for "Article 2(1) of Commission Regulation (EC) No 1234/2008" substitute "regulation 8(1) of the Human Medicines Regulations", and

(iv) at the appropriate places insert—

""Annex I to the 2001 Directive" has the meaning given by regulation 8(1) of the Human Medicines Regulations;";

""biological medicinal product" has the meaning given in paragraph 3.2.1.1. (b) of Part I of Annex I to the 2001 Directive;";

""the Committee for Medicinal Products for Human Use" means the committee established under Article 5(1) of Regulation (EC) No 726/2004;";

""the EMA" means the European Medicines Agency established by Regulation (EC) No 726/2004;"; and

(b) after paragraph 4 insert—

"**5.**—(1) For the purpose of these Regulations, a company is a medium 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 465(3) of the Companies Act 2006(**1**) (qualification of company as medium) and the conditions in sub-paragraph (2) are met.

(2) The conditions for the purposes of sub-paragraph (1) are—

(a) the company's balance sheet total as defined in section 465(5) of the Companies Act 2006 is not more than the amount for the time being specified in item 2 in section 465(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 465(3) of that Act.

(3) In this paragraph "financial year" is to be construed in accordance with section 390 of the Companies Act 2006.".

Amendment of Schedule 2 (capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates)

7.—(1) Schedule 2 is amended as follows.

(2) In paragraph 4(a), for "Article 2(4) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations".

(3) In paragraph 22—

(a) in sub-paragraph (1), for "Article 2(5) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations";

(b) in sub-paragraph (2)(f), for "Article 2(4) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations"; and

(c) in sub-paragraph (3), for "Article 2(2) of Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations".

(4) In paragraph 23—

(a) in sub-paragraph (a), for "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" substitute "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 apply";

(**1**) Section 465 was amended by S.I. 2015/980

(b) in sub-paragraph (b), for "Article 2(3) of Commission Regulation Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations"; and

(c) in sub-paragraph (c), for "Commission Regulation (EC) No 1234/2008" substitute "paragraph 1 of Schedule 10A to the Human Medicines Regulations".

(5) For the table in paragraph 24, substitute—

"**Fees for marketing authorisation applications**

Column 1 *Kind of application*	*Column 2* *Fee payable*
1. Major application	
(a) in respect of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use and in relation to which the applicant has provided such information relating to that opinion as has been requested by the licensing authority	£62,421
(b) in any other case	£92,753
2. Complex application	
(a) in respect of an application to which regulation 53 of the Human Medicines regulations applies, relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use and in relation to which the applicant has provided such information relating to that opinion as has been requested by the licensing authority	£17,330
(b) in any other case	£25,643
3. Standard application	£9,402
4. Simple application	£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".

(6) After paragraph 24, insert—

"**Fees where an application for a European Union marketing authorisation had been made before exit day**

24A.—(1) This paragraph applies where, before exit day—

(a) an application has been made to the EMA for a European Union marketing authorisation;

(b) day 120 has passed; and

(c) no final decision has been made by the European Commission in relation to the grant of an European Union marketing authorisation under Article 10 of Regulation (EC) No 726/2004.

(2) Where this paragraph applies and the applicant for the European Union marketing authorisation applies for a UK marketing authorisation in accordance with paragraph 31(2) of Schedule 33A to the Human Medicines Regulations, the fee payable under regulation 12(1) shall be waived.

(3) In this paragraph, "day 120" means the day during the assessment of an application for a European Union marketing authorisation on which the Committee for Medicinal Products for Human Use adopts the list of questions, as well as the overall conclusions and review of the scientific data, to be sent to the applicant.".

(7) In paragraph 27—

(a) in sub-paragraph (2), for paragraphs (a) to (c) substitute—

"(a) in respect of the first or only marketing authorisation applied for by that secondary applicant—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or

(ii) in any other case, the amount payable in respect of a complex application under paragraph 24;

(b) in respect of each additional marketing authorisation applied for by that secondary applicant which relates to a medicinal product of the same dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24;

(c) in respect of the first additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or

(ii) in any other case, the amount payable in respect of a complex application under paragraph 24;

(d) in respect of any other additional marketing authorisation applied for by that secondary applicant relating to that medicinal product which is of a different dosage form—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24."; and

(b) in sub-paragraph (3), for paragraph (a), substitute—

"(a) where the amount payable by the primary applicant is that in respect of a complex application, the fee payable under regulation 12(1)(a) by the secondary applicant is—

(i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24;".

(8) In paragraph 28—

(a) in sub-paragraph (2), for paragraphs (a) to (c) substitute—

"(a) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form with a different route of administration—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £17,330; or

(ii) in any other case, the amount payable in respect of a complex application under paragraph 24;

(b) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form but with the same route of administration—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24; and

(c) in respect of each additional marketing authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients—

(i) in the case of an application relating to a medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24."; and

(b) in sub-paragraph (3), for paragraphs (b) and (c), substitute—

"(b) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form but with the same route of administration—

(i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24; and

(c) in respect of each additional marketing authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients—

(i) in the case of an application relating to a biological medicinal product that has received an opinion favourable to the granting of a marketing authorisation from the Committee for Medicinal Products for Human Use, £6,350; or

(ii) in any other case, the amount payable in respect of a standard application under paragraph 24.".

(9) In paragraph 38—

(a) for sub-paragraph (4) substitute—

"(4) In sub-paragraph (1), the appropriate table is—

(a) in respect of a reclassification variation application, Table 3;

(b) in any other case, Table 2."; and

(b) omit table 1.

(10) In paragraph 39—

(a) in sub-paragraph (1), after "Subject to sub-paragraph (3)" insert "and paragraph 39A";

(b) in sub-paragraph (2), for "in respect of an orphan medicinal product", substitute "an orphan marketing authorisation"; and

(c) in sub-paragraph (3), for "an orphan medicinal product" substitute "a medicinal product which meets the orphan criteria listed in regulation 50G(2) of the Human Medicines Regulations".

(11) After paragraph 39, insert—

"**Variation of orphan marketing authorisations: small and medium companies**

39A.—(1) Subject to sub-paragraph (2), if an application to vary an orphan marketing authorisation is made by, or on behalf of, a small or a medium company within 12 months of the date of grant of the marketing authorisation, the fee payable for that variation application shall be waived.

(2) Sub-paragraph (1) does not apply to an application to authorise use of the medicinal product in a new therapeutic area which does not meet the orphan criteria listed in regulation 50G(2) of the Human Medicines Regulations.".

(12) After paragraph 40, insert—

"**Fees where an application for a variation or an extension of a European Union marketing authorisation had been made before exit day**

40A.—(1) Paragraph (2) applies where, before exit day—

(a) an application for a variation to which paragraph 11(7) of Schedule 33A to the Human Medicines Regulations applies, has been made to the EMA; and

(b) the Committee for Medicinal Products for Human Use has adopted a request for supplementary information to be sent to the applicant, or, in the case of an extension, day 120 has passed.

(2) Where this paragraph applies and the holder of a converted EU marketing authorisation submits the application to the licensing authority in order to have the variation made to the converted EU marketing authorisation, the fee payable under regulation 19(1) shall be waived.

(3) In this paragraph—

"day 120" means the day during the assessment of an extension on which the Committee for Medicinal Products for Human Use adopts the list of questions, as well as the overall conclusions and review of the scientific data, to be sent to the applicant;

"converted EU marketing authorisation" has the meaning given in paragraph 6(1) and (2) of Schedule 33A to the Human Medicines Regulations; and

"extension" has the meaning given in paragraph 1 of Schedule 10A to the Human Medicines Regulations.".

(13) For Part 6 substitute—

"PART 6

Capital Fee for the Renewal of a Marketing Authorisation

Renewal of a marketing authorisation

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 £9,682.

Renewal of multiple marketing authorisations

57.—(1) This sub-paragraph applies if more than one application falling within regulation 27A is made by the same applicant at the same time, each of which relates to medicinal products which have the same active ingredient or combination of ingredients, dosage form and therapeutic indications, and the marketing authorisations for those products have the same date for renewal.

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

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

(b) £747 for each other application.

PART 6A

Capital Fee for Conducting a Major Safety Review

57A. The fee payable under regulation 19D(1) in connection with the carrying out of a major safety review is—

(a) £51,286, where one or two active ingredients, or combinations of active ingredients, are included in the assessment;

(b) £59,595, where three active ingredients, or combinations of active ingredients, are included in the assessment;

(c) £67,904, where four active ingredients, or combinations of active ingredients, are included in the assessment; or

(d) £76,213, where five or more active ingredients, or combinations of active ingredients, are included in the assessment.

PART 6B

Capital Fee for Testing of Samples by the Appropriate Authority

57B.—(1) Unless sub-paragraph (2) applies, the fee payable under regulation 19F(1) in connection with the submission of a sample of a batch of a medicinal product of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

(2) This sub-paragraph applies where—

(a) the holder of the marketing authorisation submits, with a sample of a batch of medicinal product, a certificate issued by a laboratory in a designated country for batch testing and certification of biological medicinal products that relates to the sample of the batch submitted; and

(b) on the basis of the documentation submitted with the sample, the appropriate authority considers that it is only necessary to carry out a paper based assessment of the sample.

(3) Where sub-paragraph (2) applies, the fee payable under regulation 19F(1) in connection with the submission of a sample of a batch of medicinal product of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 3 of that table.

(4) Where a product falls within more than one of the Bands referred to in the following table, the product is to be treated as if it only falls within the Band which attracts the highest fee.

Fees for testing of samples

Column 1 *Product Type*	*Column 2* *Fee payable where the licensing authority carries out a full assessment*	*Column 3* *Fee payable where the licensing authority carries out a paper-based assessment*
1. Plasma pools which require—		
(a) three or fewer tests	£180	£90
(b) four or five tests	£215	£90
(c) six or more tests	£230	£90
2. Band A	£1,660	£305
3. Band B	£1,910	£305
4. Band C	£2,340	£305
5. Band D	£3,690	£677
6. Band E	£6,410	£677
7. Band F	£10,350	£677

(5) In this paragraph—

"Band A" means a single component product, other than Botulinum toxin, requiring five or fewer in vitro tests;

"Band B" means Factor VIII, Factor IX or intravenous Immunoglobulin;

"Band C" means a multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests;

"Band D" means a product requiring six to nine in vitro tests;

"Band E" means a product requiring—

(a) ten or more in vitro tests, or

(b) one or more in vivo tests;

"Band F" means a product—

(a) which requires one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under the Control of Substances Hazardous to Health Regulations 2002(**2**); or

(b) requires the use of human cells or tissues as part of its testing;

"Multi-component product" means a product containing two or more analytes that require testing; and

"Single component product" means a product containing a single analyte that requires testing."

Amendment of Schedule 4 (periodic fees for licences)

8. In Schedule 4, in paragraph 1, in the definition of "limited use drug" for "which is in respect of an orphan medicinal product" substitute "in respect of which an orphan marketing authorisation has been granted".

Amendment of Schedule 7 (waiver, reduction or refund of capital fees)

9. In Schedule 7, after paragraph 7, insert—

"**Orphan marketing authorisation**

7A. Where the licensing authority grants an orphan marketing authorisation, the following percentage of the fee otherwise payable under regulation 12(1)(a) in connection with the application for that authorisation shall be refunded or, if it has not yet been paid, shall be waived—

(a) in the case of an application made by or on behalf of a small or medium company, 100%;

(b) in the case of a major application that is not made by or on behalf of a small or medium company but to which paragraph 6 of Part II of Annex 1 to the 2001 Directive applies, 50%; or

(c) in any other case, 10%.".

Amendment of Schedule 8 (Adjustment, reduction or refund of periodic fees)

10.—(1) Schedule 8 is amended as follows.

(2) In the heading, after "Adjustment", insert ", waiver".

(3) After paragraph 2, insert—

(**2**) S.I. 2002/2677

"**Waiver or refund: converted EU marketing authorisations**

2A.—(1) Where the licensing authority revokes a converted EU marketing authorisation in accordance with paragraph 6(3) of Schedule 33A to the Human Medicines Regulations, the periodic fee payable under regulation 38(1) in relation to that authorisation shall be refunded, or if it has not yet been paid, shall be waived.

(2) In this paragraph, "converted EU marketing authorisation" has the meaning given in paragraph 6(1) and (2) of Schedule 33A to the 2012 Regulations."

Savings

11.—(1) The provisions of the Medicines (Products for Human Use) (Fees) Regulations 2016 ("the 2016 Regulations") omitted, substituted or amended by this Schedule shall continue to apply as if they had not been omitted, substituted or amended in relation to—

(a) capital fees payable under the 2016 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 2016 Regulations in relation to the fee period during which these Regulations come into force or in relation to a fee period ending before the date on which these Regulations come into force.

(2) The omissions, substitutions and amendments shall not affect any proceedings under the 2016 Regulations for the recovery of any fees due as debts to the Crown and for the purposes of those proceedings, the provisions omitted, substituted or amended by this Schedule shall continue to apply as if they had not been omitted, substituted or amended.