SCHEDULE 1

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

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";

(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		*Column 2*
Kind of application		*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		

Column 1		*Column 2*
Kind of application		*Fee payable*
(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(**1**); 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."

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