SCHEDULE 2

CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, MARKETING AUTHORIZATIONS, LICENCES, AUTHORISATIONS, REGISTRATIONS AND CERTIFICATES

PART 4

Capital Fees for Applications for Variations of Authorizations, Licences and Registrations

Marketing authorizations

35.—(1) Subject to paragraphs 36 to 39 and 46 to 48, the fee payable under regulation 18(1) in connection with an application for a variation to the terms of a marketing authorization of a kind described in column 1 of the appropriate table is the fee specified in the corresponding entry in column 2 of the appropriate table.

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

(a) in respect of an application for a variation of a marketing authorization which is within the scope of EC Regulation No. 1234/2008(**1**), Table 1;

(b) in respect of a UK national variation application, Table 2;

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

(3) In Table 1, "reference authority" has the meaning given in Article 20(2)(b) of EC Regulation No. 1234/2008.

(4) In Table 2, "UK national variation application" means a variation to a notification of, or an application for, a variation to the terms of a marketing authorization which is not within the scope of EC Regulation No. 1234/2008 and which—

(a) is a change set out in the document entitled "UK National MA Variations Guidance" published by the licensing authority and available on its website on 30th November 2009(**2**); and

(b) complies with the procedures and conditions to be fulfilled as set out in that document,

and the expressions "National Type 1B Application", "National Type II Application", "National Type II Complex Variation Application", "National Type II Extended Complex Variation Application", "National Type IB Minor Variation Group Application", "National Type II Major Variation Group Application" and "National Type II Major Variation Complex Group Application" shall be interpreted accordingly.

(**1**) See Article 1 of the Regulation.
(**2**) A copy of the guidance can be downloaded from the licensing authority's website at www.mhra.gov.uk or obtained by writing to the licensing authority at 151 Buckingham Palace Road, London, SW1W 9SZ or by sending an email to info@mhra.gsi.gov.uk.

Table 1

Fees for applications for variations of marketing authorizations falling within the scope of EC Regulation No. 1234/2008

Column 1			*Column 2*
Kind of variation			*Fee payable*
1. Application for a single kind variation			
(a)	Type IB Application where—		
	(i)	the UK is a concerned Member State	£300
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£594
(b)	Type II Application where—		
	(i)	the UK is a concerned Member State	£794
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£962
(c)	Type II Complex Variation Application where—		
	(i)	the UK is a concerned Member State	£8,981
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£15,571
(d)	Extended Type II Complex Variation Application where—		
	(i)	the UK is a concerned Member State	£27,716
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£38,744
2. Applications for a Group			
(a)	Minor Variation (Type IB) Group Application where—		
	(i)	the UK is a concerned Member State	£672
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£1,324
(b)	Major Variation (Type II) Group Application where—		
	(i)	the UK is a concerned Member State	£1,786
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£2,158
(c)	Major Variation (Type II) Complex Group Application where—		

Column 1			*Column 2*
Kind of variation			*Fee payable*
	(i)	the UK is a concerned Member State	£9,738
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£16,465
(d)	Major Variation (Type II) Extended Complex Group Application where—		
	(i)	the UK is a concerned Member State	£28,401
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£39,693

Table 2

Fees for UK national variation applications

Column 1	*Column 2*
Kind of national variation	*Fee payable*
1. National Type 1B Application	£300
2. National Type II Application	£794
3. National Type II Complex Variation Application	£8,981
4. National Type II Extended Complex Variation Application	£27,716
5. National Type IB Minor Variation Group Application	£672
6. National Type II Major Variation Group Application	£1,786
7. National Type II Major Variation Complex Group Application	£9,738
8. National Type II Major Variation Extended Complex Group Application	£28,401

Table 3

Fees for reclassification variation applications

Column 1		*Column 2*
Kind of reclassification variation		*Fee payable*
Application falling within the category described in—		
(a)	paragraph 15(a)	£12,961
(b)	paragraph 15(b)	£8,822

Variation of marketing authorizations

36.—(1) Subject to sub-paragraph (3), if an application to vary a marketing authorization of a kind described in sub-paragraph (2) is—

(a) the first application to vary a marketing authorization;

(b) made within 5 years of the date of grant of the marketing authorization; and

(c) an application to authorise use of the medicinal product in a new therapeutic area,

the fee payable for that application is the fee payable under regulation 18(1) together with the difference between that fee and the fee which would have been payable if the application had been a major application.

(2) In this paragraph a marketing authorization is one which has been granted in accordance with an application to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of an orphan medicinal product.

(3) Sub-paragraph (1) and (2) shall not apply where the first application for variation of the marketing authorization relates to a therapeutic area, in respect of which the applicant would be entitled (had the applicant not already held a marketing authorization) to apply for a marketing authorization to which point 6 of Part II of Annex I to the 2001 Directive applies or which is in respect of an orphan medicinal product.

Reclassification of marketing authorizations

37.—(1) Where an application is a reclassification variation application to which this paragraph applies, the fee payable under regulation 18(1) in connection with the application for variation of a marketing authorization is £794.

(2) This paragraph applies to a reclassification variation application which would have the effect that a medicinal product to which the marketing authorization relates—

(a) is to be available only from a pharmacy (where previously it was available only on prescription), if an analogous medicinal product is available only from a pharmacy or on general sale; or

(b) is to be available on general sale (where previously it was available only on prescription or only from a pharmacy), if an analogous medicinal product is available on general sale.

(3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorization or a European Union marketing authorization and which—

(a) has the same active ingredient, route of administration and use;

(b) has the same strength or a higher strength;

(c) has the same dosage or daily dosage, or a higher dosage or daily dosage; and

(d) is for sale or supply at the same quantity or a greater quantity,

as the medicinal product in relation to which the variation application is made.

Variation of marketing authorization: national homoeopathic products

38. The fee payable under regulation 18(1) in connection with an application for a variation of a marketing authorization in respect of a national homoeopathic product is—

(a) £263 where the application is a standard variation application for a homoeopathic medicinal product;

(b) £408 where the application is a new indication variation application; and

(c) £133 for any other application.

Variation of parallel import licence

39.—(1) The fee payable under regulation 18(1) in connection with an application for variation of a parallel import licence is—

(a) £13,595 if, were the marketing authorization not a parallel import licence, the application for the variation would be a reclassification variation application falling within paragraph 15(a) and to which paragraph 37 of this Schedule does not apply;

(b) £9,252 if, were the marketing authorization not a parallel import licence, the application for the variation would be a reclassification variation application falling within paragraph 15(b) and to which paragraph 37 of this Schedule does not apply; and

(c) £386, in any other case other than where the variation applied for is an administrative variation.

(2) For the purposes of sub-paragraph (1)(c) an application for an administrative variation is where the variation applied for falls within one of the following paragraphs—

(a) a change of either or both of the name and the address of the holder of the licence;

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the licence where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, and any change of address does not involve a change of the site of manufacture, assembly or storage or of the site from which distribution takes place;

(c) the removal from the licence of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;

(d) the removal from the licence of details of any of the activities to which the licence relates;

(e) the removal from the licence of details of any of the medicinal products which the holder of the licence is authorized to import;

(f) the addition or deletion of the name and address of the suppliers of the medicinal product to which the licence relates, or a change in the name, the address, or both the name and address, of the suppliers of that product; or

(g) unless paragraph 8 of Schedule 6 applies, a change consequential upon any or any combination of the following—

(i) a change of ownership of the United Kingdom marketing authorization in respect of which the parallel import licence was granted,

(ii) a change to the number of the United Kingdom marketing authorization in respect of which the parallel import licence was granted,

(iii) a change to the name of the holder of the United Kingdom marketing authorization in respect of which the parallel import licence was granted,

(iv) a change to the address of the holder of the United Kingdom marketing authorization in respect of which the parallel import licence was granted,

(v) a change to the number of the marketing authorization for the product in the country where the product originates,

(vi) a change of ownership of the marketing authorization for the product in the country where the product originates,

(vii) a change to the name of the holder of the marketing authorization for the product in the country where the product originates, or

(viii) a change to the address of the holder of the marketing authorization for the product in the country where the product originates,

where the change has been occasioned by the taking over of an existing business, whether by purchase, merger or otherwise, if the marketing authorization was not a parallel import licence, the application for that variation would be a reclassification variation application to which paragraph 38 of this Schedule applies.

Manufacturer's authorisations and licences

40. Unless the fee in paragraph 41 is payable or paragraph 46 applies, the fee payable under regulation 18(1)(c) or (d) in connection with an application for variation of a manufacturing authorisation or a manufacturer's licence is—

(a) £250 in the case of a manufacturer's licence referred to in paragraph 30(2); and

(b) £500 in any other case.

Variation of manufacturer's authorisations and licences

41. The fee payable under regulation 18(1)(c) or (d) in connection with an application for variation of a manufacturing authorisation or a manufacturer's licence is £250 in respect of each variation applied for which constitutes a change to the authorisation or licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Wholesale dealer's licences

42. Unless the fee in paragraph 43 is payable or paragraph 46 applies, the fee payable under regulation 18(1)(c) in connection with an application for a variation of a wholesale dealer's licence is £473.

Variation of wholesale dealer's licence

43. The fee payable under regulation 18(1)(c) in connection with an application for variation of a wholesale dealer's licence is £250 in respect of each variation applied for which consists of a change to the licence not requiring an inspection or medical, scientific or pharmaceutical assessment.

Clinical trial authorisations

44.—(1) The fee payable under regulation 19(1) in connection with a notice of amendment relating to amendment to the dossier accompanying a request for authorisation to conduct a clinical trial is—

(a) £265 if the amendments relate to one of the parts of the dossier specified in sub-paragraph (2) only;

(b) £530 if the amendments relate to two parts of the dossier specified in sub-paragraph (2) only; or

(c) £795 if the amendments relate to all three parts of the dossier specified in sub-paragraph (2) only.

(2) The parts of the dossier specified in sub-paragraph (1) are—

(a) the part containing the summaries of the chemical, pharmaceutical and biological data relating to the medicinal product tested or used in the trial;

(b) the part containing the summaries of the non-clinical, pharmacological and toxicology data on that product; and

(c) the part containing the summaries of the available data from previous clinical trials of, and human experience with, that product.

Traditional herbal registrations

45. Unless paragraph 46 applies, the fee payable under regulation 18(1) in connection with an application for variation of a traditional herbal registration is—

(a) £260 if the application is a standard variation application;

(b) £687 if the application is a complex variation application;

(c) £7,767 if the application is a new excipient variation application; and

(d) £164 if the application is an administrative variation application.

Identical variations

46.—(1) Unless paragraph 47 or 48 applies, where more than one application—

(a) of a type referred to in sub-paragraph (2) is made at the same time by the same marketing authorization holder and all of the applications are for identical kinds of variations; or

(b) by the same applicant is made at the same time for a traditional herbal registration, a manufacturer's licence, or a wholesale dealer's licence and where the applications are for identical variations,

the fee payable under regulation 18(1) is that specified in sub-paragraph (3).

(2) The type of application referred to in sub-paragraph (1) is a—

(a) Type IB Application;

(b) Type II Application;

(c) Minor Variation (Type IB) Group Application; or

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

(3) The fee referred to in sub-paragraph (1)—

(a) in connection with the first application considered by the licensing authority is the appropriate amount specified in this Part of this Schedule; and

(b) in connection with each of the other applications is 50% of that amount.

Complex Variation Applications

47.—(1) Where more than one application of a type referred to in sub-paragraph (2) is made at the same time by the same marketing authorization holder and all of the applications are for identical kinds of variations, the fee payable under regulation 18(1)—

(a) in connection with the first application considered by the licensing authority is the appropriate amount specified in this Part of the Schedule; and

(b) in connection with each of the other applications in respect of which no further medical, scientific or pharmaceutical assessment is required, is the amount which would be payable if the application was a Type II Application.

(2) The type of application referred to in sub-paragraph (1) is a—

(a) Type II Complex Variation Application;

(b) Extended Type II Complex Variation Application;

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

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

Multiple reclassification variation applications

48. Where more than one reclassification variation application is made at the same time by the same applicant, each relating to medicinal products which have the same active ingredient or combination of ingredients, the fee payable under regulation 18(1)—

(a) if one or more of the applications is an application to which paragraph 37 does not apply—

(i) in connection with the first application to which paragraph 37 does not apply, is the appropriate amount specified in this Part of the Schedule;

(ii) in connection with each other application to which paragraph 37 does not apply, the fee payable is £794; and

(iii) in connection with each other application to which paragraph 37 does apply, the fee payable is £397; and

(b) in any other case—

(i) in connection with the first application, is the appropriate amount specified in this Part of the Schedule; and

(ii) in connection with each other application, the fee payable is £397.