SCHEDULE 1 Regulations 2 (1), 12 (1) (a), 16, 18(1), 19 (1), 22(1), 26(1).

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

PART 1

Interpretation

1. In this Schedule—

"active ingredient" means an ingredient of a medicinal product in respect of which efficacy is claimed (whether therapeutic, diagnostic or otherwise);

"active ingredient from a new source" means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

"certificate of registration" means a certificate for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**1**);

"complex application" means an application, other than a major application, for a marketing authorization where the application falls within one or more of the descriptions specified in sub-paragraphs (a) to (s)—

(a) the application relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a new category of patients or as treatment for a new category of disease;

(b) the application relates to a medicinal product containing a new combination of active ingredients that have not previously been included in that combination in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(c) the application relates to a medicinal product containing a new excipient;

(d) the application relates to a medicinal product that is intended to be administered by a route of administration different from that used in the administration of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(e) the application relates to a medicinal product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a medicinal product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(f) the application relates to a medicinal product which is a controlled release preparation and is not a simple application;

(g) the application relates to a sterile medicinal product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any medicinal product which contains the same active ingredient as the product in question and in

(**1**) S.I. 1994/105; relevant amending instruments are S.I. 1996/482, 2005/2753, 2006/494 and 2007/610.

respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(h) the application relates to a sterile medicinal product the container of which is directly in contact with the medicinal product and is made from different material from the container of any medicinal product which contains the same active ingredient as the product in question and in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(i) unless a European Pharmacopoeia certificate of suitability covering the active ingredient has been submitted with the application, the application names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(j) the application relates to a medicinal product which is an influenza vaccine and in respect of which the manufacturer or the manufacturing process is different from that specified in any other marketing authorization which the application holds in respect of that product;

(k) the application is for the grant of a marketing authorization for a medicinal product which is an influenza vaccine, except where it relates only to an influenza vaccine containing a different strain or strains from that specified in any other marketing authorization which the applicant holds;

(l) the application is for the grant of a marketing authorization for a medicinal product which is to be delivered by way of a metered dose inhaler;

(m) the application is for the grant of a marketing authorization for a medicinal product which is in a powdered form and is to be delivered by way of inhalation;

(n) the application relates to a medicinal product—

(i) which is administered to the site of action or absorption by a method which has not previously been authorised in relation to any authorised medicinal product which contains the same active ingredient as the product in question, and

(ii) in respect of that other product, a marketing authorization (other than a product licence of right) has previously been granted;

(o) the application is an application for a marketing authorization to which Article 10(3) of the 2001 Directive applies;

(p) the application is an application where the sole or primary evidence for the safety and efficacy of the medicinal product consists of published scientific literature;

(q) the application is—

(i) for an extension of an existing marketing authorization which fulfils the conditions set out in Annex II to Commission Regulation (EC) No. 1084/2003, and

(ii) includes the result of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive;

(r) the application—

(i) is not an application in accordance with Article 10, 10a or 10c of the 2001 Directive, and

(ii) includes the results of pre-clinical tests or clinical trials as specified in Article 8(3)(i) of the 2001 Directive;

(s) the application is an application for a marketing authorization to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applies;

"complex registration application" means an application for a traditional herbal registration relating to a medicinal product containing an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

"decentralised procedure application" means a major application, a complex application, a standard application or a simple application for a marketing authorization for a medicinal product in respect of which at the time of the application—

(a) a marketing authorization has not been granted in any EEA State; and

(b) an application for a marketing authorization has been made in more than one EEA State pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive;

"EC marketing authorization" means—

(a) a marketing authorization, or

(b) an authorization issued by the competent authorities of an EEA State other than the United Kingdom for the purposes of Article 6 of the 2001 Directive;

"eCTD format" means the electronic format of the Common Technical Document referred to in the guidance published by the European Commission in Volume 2B of "The Rules Governing Medicinal Products in the European Union", referred to in paragraph (1) of the Introduction to Annex I to the 2001 Directive;

"eCTD format application" means an application made using the MHRA portal and in relation to which the accompanying particulars and documents are presented in eCTD format;

"European reference product application" means an application for a marketing authorization to which the third sub-paragraph of Article 10(1) of the 2001 Directive applies;

"major application" means an application for a marketing authorization relating to a medicinal product containing a new active ingredient;

"the MHRA portal" means the internet-based hosted platform which enables persons to carry out business with the Medicines and Healthcare products Regulatory Agency of the Department of Health electronically, known as the "the MHRA Portal";

"mutual recognition procedure incoming application" means a major application, a complex application, or a standard application for a marketing authorization for a medicinal product in respect of which—

(a) a marketing authorization has already been granted in another EEA State; and

(b) recognition of that marketing authorization is sought from the licensing authority by way of the grant of a marketing authorization in the United Kingdom, pursuant to the procedure in Title III, Chapter 4 of the 2001 Directive;

"new active ingredient" means an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

"new excipient" means—

(a) except in Part 2, paragraph 11 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—

  (i) which is intended to be administered by the same route of administration as the product in question, and

  (ii) in respect of which a marketing authorization (other than a product licence or right), a certificate of registration or a traditional herbal registration has previously been granted,

except that in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product;

(b) in Part 2, paragraph 11 and Part 4, any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorization (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted, except that—

(i) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product, and

(ii) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in a cosmetic product;

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

"Phase II or Phase III trial" means a clinical trial, other than a Phase I trial, where the medicinal product being tested—

(a) does not have an EC marketing authorization; or

(b) has an EC marketing authorization, but—

(i) there has been a change—

(aa) to the process of manufacture of the product or its active ingredient, or

(bb) of manufacturer of that product or substance, or

(ii) the product is to be used in the trial other than in accordance with the terms of the summary of product characteristics under that authorization;

"Phase IV trial" means a clinical trial other than a Phase I trial or a Phase II or Phase III trial;

"reduced registration application category I" means an application other than a complex registration application for a traditional herbal registration relating to a medicinal product which is presented in the form of a herbal tea;

"reduced registration application category II" means an application, other than a complex registration application, or a traditional herbal registration where the application falls within one of the descriptions specified in sub-paragraphs (a) to (d) as follows—

(a) the application relates to a medicinal product which is presented in the form of a herbal tincture;

(b) the application relates to a medicinal product which is presented in the form of an essential oil;

(c) the application relates to a medicinal product which is presented in the form of a fatty oil; or

(d) the application relates to a medicinal product which contains only herbal substances in a capsule;

"simple application" means—

(a) an application for a marketing authorization to which Article 10c of the 2001 Directive applies; or

(b) an application made no later than three months after the expiry of a marketing authorization, which is for a marketing authorization containing identical provisions to those contained in the expired authorization and which is made by the person who held the expired authorization;

"standard application" means any application for the grant of a marketing authorization which is not a major application, a complex application, a simple application, a change of ownership application or an application for a parallel import licence;

"standard registration application" means any application for the grant of a traditional herbal registration which is not a complex registration application, a reduced registration application category I, a reduced registration application category II or a change of ownership application;

"TSE risk ingredient from a new source" and "TSE risk excipient from a new source" mean an active ingredient or excipient, respectively, which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

(a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that ingredient or excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted; and

(b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

"vitamin or mineral from a new source" means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted.

PART 2

Capital Fees for Applications for Authorizations, Licences and Certificates

Marketing authorizations

2.—(1) Unless paragraphs 3, 4, 6 or 7 apply, the fee payable under regulation 12(1)(a) in connection with an application for a marketing authorization of a kind described in column 1 of the following table is—

(a) if the application is an eCTD format application, the fee specified in the corresponding entry in column 2 of that table; or

(b) if the application is not an eCTD format application, the fee specified in the corresponding entry in column 3 of that table.

Fees for marketing authorization applications

Column 1 *Kind of application*		*Column 2* *Fee payable if application is in eCTD format*	*Column 3* *Fee payable if application is not in eCTD format*
1. Major application			
(a)	in respect of an application relating to an orphan medicinal product to which point 6 of Part 2 of Annex 1 to the 2001 Directive applies	£30,101	£31,576
(b)	which is a mutual recognition procedure incoming application	£63,198	£66,295
(c)	which is a European reference product application	£63,198	£66,295
(d)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£90,671	£95,114
(e)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£138,145	£144,914
(f)	in any other case	£93,907	£98,491
2. Complex application			
(a)	which is a mutual recognition procedure incoming application	£17,546	£18,406
(b)	which is a European reference product application	£17,546	£18,406
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£25,068	£26,296
(d)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£40,461	£42,444
(e)	in any other case	£25,962	£27,228
3. Standard application			
(a)	which is a mutual recognition procedure incoming application	£6,430	£6,745
(b)	which is a European reference product application	£6,430	£6,745
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£9,191	£9,642
(d)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£17,779	£18,650

Column 1 *Kind of application*	*Column 2* *Fee payable if application is in eCTD format*	*Column 3* *Fee payable if application is not in eCTD format*
(e) in any other case	£9,519	£9,984
4. Simple application		
(a) which is a decentralised procedure application where the United Kingdom is a concerned member State	£2,596	£2,722
(b) in any other case	£2,596	£2,722
5. Application for a parallel import licence	*Not applicable*	£1,815
6. Change of ownership application	*Not applicable*	£448

(2) Each reference in paragraphs 3, 5 and 6 to an amount payable under paragraph 2 in respect of an application refers to the amount payable under that paragraph in respect of an application of the kind in question.

Fees where application includes reclassification

3.—(1) Unless paragraph 5 applies, where an application, other than a major application, includes a reclassification element, an amount of –

(a) £8,264 if the application is an eCTD format application; or

(b) £8,666, if the application is not an eCTD format application,

is payable in addition to the amount payable under paragraph 2 in respect of that application.

(2) For the purposes of this paragraph and paragraph 6, an application includes a reclassification element if—

(a) the medicinal product in question is to be available in the United Kingdom only from a pharmacy, unless there is an analogous medicinal product available in the United Kingdom only from a pharmacy or on general sale; or

(b) the medicinal product in question is to be available in the United Kingdom on general sale, unless there is an analogous medicinal product also so available.

(3) For the purposes of this paragraph, an analogous medicinal product is a medicinal product which has a United Kingdom marketing authorization or a Community 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 application is made.

Fees where person holds clinical trial certificate

4. Where a major application is made by a person who holds a clinical trial certificate for a medicinal product which contains the same active ingredient as the medicinal product in respect of which the marketing authorization is applied for, the fee payable under regulation 12(1)(a) in

connection with the application is reduced by the amount of the application fee paid for the clinical trial certificate.

Joint development

5.—(1) In this paragraph—

"joint development" means the development by two or more applicants for marketing authorizations relating to medicinal products—

(a) each of which contains the same new active ingredient or combination of new active ingredients but with different proprietary names and which does not require separate consideration by a committee established under section 4 (establishment of committees) of the Act or by the Commission; and

(b) the development of which has been notified to the licensing authority at or before the time the application is submitted, as being a joint development undertaken by those applicants; and

(c) in respect of which applications for marketing authorizations have been received by the licensing authority within one month of each other;

"primary applicant" means—

(a) that party to a joint development who first makes an application for a marketing authorization relating to a new active ingredient which was the subject of that joint development; or

(b) that party to a joint development who first makes an application for a marketing authorization relating to a different dosage form or strength of that new active ingredient;

"secondary applicant" means any party to a joint development, other than the primary applicant, who makes an application for a marketing authorization relating to the same new active ingredient as that which was the subject of the application made by the primary applicant.

(2) Unless sub-paragraph (3) applies, where a joint development relates to a medicinal product and two or more applications for marketing authorizations are submitted to the licensing authority by parties to the joint development, the fee payable under regulation 12(1)(a) is the amount payable in respect of a major application under paragraph 2 plus—

(a) in respect of the first or only marketing authorization applied for by that secondary applicant, the amount payable in respect of a complex application under paragraph 2;

(b) in respect of each additional marketing authorization applied for by that secondary applicant which relates to a medicinal product of the same dosage form, the amount payable in respect of a standard application under paragraph 2;

(c) in respect of the first additional marketing authorization applied for by that secondary applicant relating to that medicinal product which is of a different dosage form, the amount payable in respect of a complex application under paragraph 2 and in respect of any other such application by that secondary applicant, the amount payable in respect of a standard application under paragraph 2.

(3) Where a joint development relates to a medicinal product and an application for an additional marketing authorization is submitted by both the primary applicant and the secondary applicant, both or all of which applications relate to identical dosage forms and strengths of the product—

(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 application is that in respect of a standard application under paragraph 2;

(b) where the amount payable by the primary applicant is that in respect of a standard application, the fee payable under regulation 12(1)(a) by the secondary applicant is that in respect of a simple application under paragraph 2.

Applications for multiple authorisations

6.—(1) Unless sub-paragraphs (2), (3) or (4) apply, where an application for a marketing authorization is for more than one such authorization each relating to a medicinal product containing the same active ingredient or combination of ingredients, the fee payable under regulation 12(1)(a) is an amount equal to the aggregate of the amounts payable under paragraph 2 in respect of a separate application for each such authorization.

(2) If the application is a major application, the amount payable is the amount payable in respect of a major application under paragraph 2 plus—

(a) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 2;

(b) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form but with the same route of administration, the amount payable in respect of a standard application under paragraph 2; and

(c) in respect of each additional marketing authorization 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, the amount payable in respect of a standard application under paragraph 2.

(3) If the application is a complex application, the amount payable is the amount payable in respect of a complex application under paragraph 2 plus—

(a) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 2;

(b) in respect of each additional marketing authorization applied for which relates to a medicinal product of a different dosage form but with the same route of administration, the amount payable in respect of a standard application under paragraph 2; and

(c) in respect of each additional marketing authorization 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, the amount payable in respect of a standard application under paragraph 2.

(4) If the application includes any applications for marketing authorizations that include a reclassification element, the amount payable is the amount payable in accordance with sub-paragraphs (1) to (3) plus—

(a) in respect of the first marketing authorization applied for that includes a reclassification element, the additional amount payable under paragraph 3(1); and

(b) in respect of each other marketing authorization applied for that includes a reclassification element, £778, except in the case of an eCTD format application in which case the additional amount payable is £744.

Authorisation for a national homoeopathic product

7.—(1) In connection with an application for a marketing authorization for a national homoeopathic product prepared from not more than 5 homoeopathic stocks, the fee payable under

regulation 12(1)(a) is the amount set out in Column (2) in the Table below opposite the description in Column (1) appropriate to that application.

(2) In connection with any other application for a marketing authorization for a national homoeopathic product, the fee payable under regulation 12(1)(a) shall be the amount set out in Column (3) in the Table below opposite the description in Column (1) appropriate to that application.

(3) This paragraph does not apply to an application which is a mutual recognition procedure incoming application or a decentralised procedure application.

Column (1)	*Column (2)*	*Column (3)*
Description of application	*Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	*Fees for other applications*
1. An application in respect of a product which is both prepared solely from repeat stocks and is of a repeat formulation	£531	£753
2. An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£832	£1,044
3. Any other application	£1,120	£1,350

(4) Each reference in sub-paragraphs (5) to (7) to an amount payable under sub-paragraph (1) or (2) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(5) Where an application relates to a national homoeopathic product which is manufactured using a method of sterilisation—

(a) not used in the manufacture of a medicinal product in respect of which a marketing authorization (other than a product licence of right), a certificate of registration or a traditional herbal registration has previously been granted; and

(b) not referred to in the European Pharmacopoeia or any national pharmacopoeia of a member State,

an amount of £2,216 is payable in addition to the amount payable under sub-paragraph (1) or (2) in respect of that application.

(6) Where an application relates to a national homoeopathic product which contains one or more new excipients, an amount of £7,393 is payable in addition to the amount payable under sub-paragraph (1) or (2) in respect of that application.

(7) Where an application relates to a national homoeopathic product which contains one or more TSE risk ingredients or excipients from a new source, an amount of £653 is payable in addition to the amount payable under sub-paragraph (1) or (2) in respect of that application.

(8) In this paragraph—

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

"homoeopathic marketing authorization" means a marketing authorization granted by the licensing authority in respect of a national homoeopathic medicinal product;

"identical" means—

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

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

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

"repeat formulation" means—

(a) the formulation of a product which is identical to the formulation of another product—

(i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorization, or

(ii) to which the applicant has, by the holder of the certificate of registration or the homoeopathic marketing authorization which relates to it, been authorised in writing to make reference for the purposes of this application; or

(b) where more than one application is made by the same applicant on the same occasion in respect of products of identical formulations, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the formulation of the product to which the first of those applications which is considered by the licensing authority relates; and

"repeat stock" means—

(a) a homoeopathic stock which is identical to another homoeopathic stock which is used in the preparation of a product—

(i) in respect of which the applicant holds a certificate of registration or a homoeopathic marketing authorization, or

(ii) in respect of which another person holds a certificate of registration or a homoeopathic marketing authorization to which, for the purposes of his application, the applicant has been authorised in writing to make reference by the person (or, if more than one, each of the persons) who supplied information to the licensing authority in connection with the application for the marketing authorization which relates to that product.

Manufacturer's licences and authorisations

8.—(1) The fee payable under regulation 12(1)(a) in connection with an application for a manufacturer's licence or a manufacturing authorisation is—

(a) £169, in a case to which sub-paragraph (2) applies;

(b) £319, in the case of a change of ownership application; and

(c) £2,911, in any other case.

(2) This sub-paragraph applies to the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of medicinal products which are to be sold or supplied in circumstances to which article 2(2)(i)(e) (exemptions for certain special manufactured products) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 applies.

Wholesale dealer's licences

9.—(1) Unless sub-paragraphs (2) or (6) apply, the fee payable under regulation 12(1)(a) in connection with an application for a wholesale dealer's licence is £1,670.

(2) Where this sub-paragraph applies, the fee payable under regulation 12(1) (a) is £715.

(3) Sub – paragraph (2) applies where an application for a wholesale dealer's licence—

(a) relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than 15 per cent of the total turnover of the sale of authorised medicinal products carried on at that pharmacy;

(b) does not relate to anything done in a registered pharmacy but where the total turnover of the sale by way of wholesale dealing of authorised medicinal products does not exceed £35,000; or

(c) relates only to medicinal products falling within a description or class specified in an Order which is for the time being in force made under section 51(1) (general sale lists) of the Act(**2**).

(4) For the purposes of sub-paragraphs (3) (a) and (b) "turnover" means the gross amount of the total sales made during the period of 12 months preceding the date of the application.

(5) But sub-paragraph (2) does not apply where the applicant has not held a wholesale dealer's licence during the 12 month period preceding the date of the application unless at the time of making the application it is reasonable for the applicant to believe —

(a) in the case of an application for a wholesale dealer's licence which relates to anything done in a registered pharmacy by or under the supervision of a pharmacist and which amounts to wholesale dealing, that such dealing will constitute no more than 15 per cent of the gross amount of the total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence; or

(b) in the case of an application for a wholesale dealer's licence which does not relate to anything done in a registered pharmacy, that the gross amount of total sales of authorised medicinal products likely to be made in the period of 12 months following the grant of the licence will not exceed £35,000; and

he so informs the licensing authority when he makes his application.

(6) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £369.

Clinical trial authorisations

10.—(1) Unless sub-paragraphs (3) and (4) apply, the fee payable under regulation 12(1)(a) in connection with an application for a clinical trial authorisation for a clinical trial 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.

Column 1 *Kind of clinical trial*	*Column 2* *Fee payable*
Phase I trial	£2,146
Phase II or Phase III trial where the medicinal product being tested is unknown to the licensing authority	£4,040
Phase II or Phase III trial where the product being tested is known to the licensing authority	£3,283
Phase IV trial	£252

(2) For the purposes of that Table, a medicinal product is known to the licensing authority if—

(**2**) Section 51(1) has been amended by S.I. 2006/2407.

(a) the product has an EC marketing authorization; or

(b) the product does not have an EC marketing authorization, but where—

(i) another pharmaceutical form or strength of that product has an EC marketing authorization and the medicinal product is supplied for the purposes of the clinical trial by the holder of that authorization,

(ii) another medicinal product containing the same active substance has an EC marketing authorization and the medicinal product is supplied for the purposes of the clinical trial by the manufacturer of that other product, or

(iii) a clinical trial in which that product is, or was, being tested or used has been authorised by the licensing authority in accordance with Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (**3**).

(3) Where the application is in relation to a clinical trial in which the medicinal products being tested or used are the same as those being tested or used in a clinical trial—

(a) in respect of which the applicant made a request for authorisation; and

(b) which has been authorised by the licensing authority for the purposes of the Clinical Trials Regulations,

the fee payable in connection with that application is £252.

(4) Where—

(a) the medicinal product to be tested in the clinical trial to which the application relates has been used in another clinical trial that has been authorised, or is to be treated as having been authorised, by the licensing authority for the purposes of the Clinical Trials Regulations; and

(b) the sponsor of that other trial authorises the licensing authority to refer to the dossier submitted in relation to that product in accordance with paragraph 11 of Schedule 3 to those Regulations,

the fee payable in connection with that application is £252.

Traditional herbal registrations

11.—(1) Subject to sub-paragraphs (3) to (6), the fee payable under regulation 12(1)(a) in connection with an application for a traditional herbal registration 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—

Column 1		*Column 2*
Kind of application		*Fee payable*
1. Complex registration application		
(a)	in respect of a medicinal product containing a single active ingredient	£4,986
(b)	in any other case	£7,480
2. Standard registration application		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£2,493

(**3**) OJNo. L121, 1.5.2001, p.34. This Directive has been amended by Regulation (EC) No 1901/2006, OJ No. L 378, 27.12.2006, p.1 to which amendments which are not relevant to these Regulations have been made.

Column 1		*Column 2*
Kind of application		*Fee payable*
(b)	in any other case	£3,740
3. Reduced registration application category II		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£831
(b)	in any other case	£1,247
4. Reduced registration application category I		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£555
(b)	in any other case	£831
5. Change of ownership application		£448

(2) Each reference in sub-paragraphs (3) to (6) to an amount payable under sub-paragraph (1) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(3) Where an application relates to a medicinal product which contains one or more vitamins or minerals which are vitamins or minerals from a new source, a fee of—

(a) £1,108, if European Pharmacopoeia certificates of suitability covering all the vitamins or minerals which are a vitamin or mineral from a new source have been submitted with the application;

(b) £2,216, in any other case,

is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(4) Where an application relates to a medicinal product which contains one or more new excipients, an amount of £7,394 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(5) Where an application relates to a medicinal product which contains one or more TSE risk excipients from a new source, an amount of £657 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

(6) Where an application relates to a medicinal product which is a sterile medicinal product, an amount of £2,216 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

PART 3

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

Interpretation

12. In this Part, a reference to—

(a) an application to the licensing authority for regulatory assistance means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type,

relating to a single United Kingdom marketing authorization; and

(b) an application for a marketing authorization in a concerned member State means a reference to—

(i) a single application of that type, or

(ii) a set of applications of that type in a number of concerned member States,

relating to a single United Kingdom marketing authorization.

Outgoing mutual recognition applications

13. The fee payable under regulation 16 in connection with an application to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorization in a concerned member State is—

(a) if the application in the concerned member State, had it been in the United Kingdom, would have been a major application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £42,090, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £27,648;

(b) if the application in the concerned member State, had it been in the United Kingdom, would have been a complex application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £10,883, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £7,221;

(c) if the application in the concerned member State, had it been in the United Kingdom, would have been a standard application—

(i) in respect of the first application for regulatory assistance to the licensing authority, a fee of £4,333, and

(ii) in respect of each other application for regulatory assistance to the licensing authority, a fee of £3,611; and

(d) if the application in the concerned member State, had it been in the United Kingdom, would have been a simple application, in respect of each application for regulatory assistance to the licensing authority, a fee of £2,593.

PART 4

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

Interpretation

14. In this Part of this Schedule—

"administrative variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration where the variation applied for falls within one of the following sub-paragraphs—

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

(b) a change of either or both of the name and the address of a manufacturer, assembler, storer or distributor named in the registration 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 registration of details of one or more of the sites of manufacture, assembly or storage or of the sites from which distribution takes place;

"BROMI variation" means a notification of, or an application for, a variation to the terms of a marketing authorization which is not within the subject matter or scope of Commission Regulation (EC) No.1084/2003 and which—

(a) is submitted using the MHRA portal;

(b) is for a change set out in the BROMI variations guidance;

(c) complies with the conditions to be fulfilled set out in the check list which relates to that change in the BROMI variations guidance; and

(d) is accompanied by the documents which the BROMI variations guidance specifies must be provided with the application for the change;

"BROMI self-certification variation" means a BROMI variation for a change which is designated a Self Certification Procedure type in the check list in the BROMI variations guidance;

"BROMI Type IA variation" means a BROMI variation for a change which is designated a IA Procedure type in the check list in the BROMI variations guidance;

"BROMI Type IB variation" means a BROMI variation for a change which is designated a IB Procedure type in the check list in the BROMI variations guidance;

"BROMI variations guidance" means version 2.1 of the document published by the licensing authority on its website in February 2008, entitled "BROMI Dossier Requirements For Type IA And Type IB UK National Notifications" and dated November 2007(**4**);

"complex variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

(a) a change in that product's active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;

(b) a change in that product's excipients which involves the addition of one or more TSE risk excipients from a new source; or

(c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application;

"Extended Type II Complex Variation Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) so that the medicinal product is indicated for use—

(a) in a therapeutic area for which the product was not previously indicated for use; or

(b) in respect of an organ, or any other part, of the human body for which the product was not previously indicated for use, if the application is supported by data which comprises or includes the results of clinical trials or physico-chemical, microbiological or pharmacological and toxicological tests;

(**4**) A copy of the guidance may be downloaded from the website at www. mhra. gov.uk or may be obtained , by writing to the licensing authority at Market Towers, 1 Nine Elms Lane, London SW8 5NQ, or by sending an email to info@mhra.gsi.gov.uk.

"new excipient variation application" means an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient;

"new indication variation application" means an application to vary a marketing authorization for a national homoeopathic product, so that product is indicated for a therapeutic use not previously covered by that authorization;

"reclassification variation application" means an application for variation of a marketing authorization which has the effect that a medicinal product to which that authorization relates—

(a) is to be available only from a pharmacy, where previously it was available only on prescription; or

(b) is to be available on general sale, where previously it was available only on prescription or only from a pharmacy;

"standard variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which is not a complex variation application, a new excipient variation application or an administrative variation application;

"standard variation application for a homoeopathic product" means an application for a variation of a marketing authorization for a national homoeopathic medicinal product which requires—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(o) a change to the dimensions of an approved dosage form of the product (for example, tablets); or

(p) a change following modification to the manufacturing authorization referred to in Article 40 of the 2001 Directive;

"Type IA Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is a "minor variation" of Type IA within the meaning of Article 3.2 of Commission Regulation (EC) No. 1084/2003;

"Type IB Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is a "minor variation" of Type IB within the meaning of Article 3.2 of Commission Regulation (EC) No. 1084/2003;

"Type II Application" means an application by a marketing authorization holder to vary a marketing authorization (not being a parallel import licence) which is not—

(a) a reclassification variation;

(b) a Type IA Application;

(c) a Type IB Application;

(d) a Type II Complex Variation Application;

(e) an Extended Type II Complex Variation Application; or

(f) a change to which Annex II to Commission Regulation (EC) No. 1084/2003 applies;

"Type II Complex Variation Application" means an application for a variation of a marketing authorization, other than an Extended Type II Complex Variation Application, which relates to a change—

(a) in the formulation of a medicinal product comprising one or more of the following changes, other than a change to which paragraph 1 (changes to active substances) or paragraph 2 (changes to strength, pharmaceutical form and route of administration) of Annex II to Commission Regulation (EC) No. 1084/2003 applies—

  (i) a change which necessitates in- vivo bioavailability studies to be performed on that product,

  (ii) a change in that product's preservative system, or

  (iii) a change in that product's excipients which significantly affects the pharmaceutical or the therapeutic properties of that product; or

(b) which is considered a "major variation" within the meaning given in Article 3.3 of Commission Regulation (EC) No. 1084/2003 and which is—

  (i) supported by data which comprises or includes the results of clinical trials or physicochemical, biological, microbiological or pharmacological and toxicological tests, or

  (ii) accompanied by evidence relating to post-marketing experience which is information of any type described in paragraph 5.2.6 of Part I of Annex I to the 2001 Directive (clinical documentation); or

(c) in the composition, manufacture or use of a medicinal product to which—

  (i) paragraph (c), (e), (g), (h), (j) or (n) of the definition of complex application in this Schedule would apply where an application for a marketing authorization is made in respect of a medicinal product, or

  (ii) paragraph (i) of that definition would so apply and the change is not a variation which satisfies conditions 1, 3 and 4 specified in point 14 of Annex I to Commission Regulation (EC) No. 1084/2003 (change in the manufacturer of the active substance or starting material/reagent/intermediate in the manufacturing process of the active substance where no European Pharmacopoeia certificate of suitability is available).

Marketing authorizations

15. Subject to paragraphs 17 to 19 and 26 to 28, the fee payable under regulation 18(1) in connection with an application for a variation of a marketing authorization of a kind described in column 1 of the following table is—

(a) if the application is an eCTD format application, the fee specified in the corresponding entry in column 2 of that table;

(b) if the application is not an eCTD format application, the fee specified in the corresponding entry in column 3 of that table.

Fees for applications for variations of marketing authorizations

Column 1		*Column 2*	*Column 3*
Kind of application		*Fee payable if in eCTD format*	*Fee payable for application not in eCTD format*
1. Application where, for the purposes of Commission Regulation (EC) No. 1084/2003, the United Kingdom is the reference Member State as defined in Article 3.4 of that Regulation			
(a)	Type IA Application	£278	£292
(b)	Type IB Application	£556	£583
(c)	Type II Application	£900	£944
(d)	Type II Complex Variation Application	£14,586	£15,298
(e)	Extended Type II Complex Variation Application	£36,290	£38,062
2. Other variation applications			
(a)	BROMI Self Certification Application	£176	£178
(b)	Type IA Application	£180	£188
(c)	BROMI Type 1A Application	£180	£188
(d)	Type 1B Application	£280	£296
(e)	BROMI Type 1B Application	£280	£296
(f)	Type II Application	£744	£778
(g)	Type II Complex Variation Application	£8,412	£8,824
(h)	Extended Type II Complex Variation Application	£25,962	£27,228
(i)	Reclassification variation Application	£8,264	£8,666

Variation of marketing authorizations

16.—(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) and 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 1 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 he 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

17.—(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 £778, unless the application is an eCTD format application, in which case the fee payable under regulation 18(1) is £744.

(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 Community 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: natural homoeopathic products

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

(a) £250, where the application is a standard variation application for a homeopathic product;

(b) £388, where the application is a new indication variation application; and

(c) £127, for any other application.

Variation of parallel import licence

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

(a) £8,666 if, were the marketing authorization not a parallel import licence, the application for the variation would be a reclassification variation application to which paragraph 17 of this Schedule does not apply;

(b) £176 if the application is one to which sub-paragraph (2) applies; and

(c) £360, in any other case.

(2) This sub paragraph applies where the variation applied for falls within one of the following sub-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;

(g) unless paragraph 7 of Schedule 5 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,

(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 18 of this Schedule applies.

Manufacturer's authorisations and licences

20. Unless paragraph 26 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) £238, in the case of a manufacturer's licence referred to in paragraph 8(2) of Part 2 of this Schedule; and

(b) £476, in any other case,

unless the fee in paragraph 21 is payable.

Variation of manufacturer's authorisations and licences

21. 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 £238 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

22. Unless the fee in paragraph 23 is payable or paragraph 26 applies, the fee payable under regulation 18(1)(c) in connection with an application for a variation of a wholesale dealer's licence is £450.

Variation of wholesale dealer's licence

23. The fee payable under regulation 18(1)(c) in connection with an application for variation of a wholesale dealer's licence is £238 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

24.—(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) £252, if the amendments relate to one of the parts of the dossier specified in sub-paragraph (2) only ;

(b) £505, if the amendments relate to two parts of the dossier specified in sub-paragraph (2) only; or

(c) £757, 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 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

25. Unless paragraph 26 applies, the fee payable under regulation 18(1) in connection with an application for variation of a traditional herbal registration is—

(a) £247, if the application is a standard variation application;

(b) £654, if the application is a complex variation application;

(c) £7,394, if the application is a new excipient variation application;

(d) £156, if the application is an administrative variation application.

Identical variations

26. Unless paragraphs 27 or 28 apply, where more than one application by the same applicant is made at the same time for the variation of a marketing authorization, 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)—

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

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

Complex Variation Applications

27. Where more than one Type II Complex Variation Application or Extended Type II Complex Variation Application is made at the same time by the same applicant for the variation of a marketing authorization, 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;

(b) in connection with each of the other applications where the applications are for identical variations and 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.

Multiple reclassification variation applications

28. 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 17 does not apply—

(i) in connection with the first application to which paragraph 17 does not apply, is the appropriate amount specified in this Part of the Schedule,

(ii) in connection with each other application to which paragraph 17 does not apply, is £778, and

(iii) in connection with each other application to which paragraph 17 does apply, is £389;

(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, is £389.

PART 5

Capital Fees for Assessment of Labels and Leaflets

Interpretation

29. In this Part—

(a) "clinical particulars", in relation to a medicinal product, means the clinical particulars contained in the Summary of Product Characteristics for that product as specified in paragraph 4 of Article 11 of the 2001 Directive;

(b) the "BROMI labels and leaflets self-certification guidance" means the document entitled "Guidance on Changes to Labelling and Patient Information Leaflets For Self – Certification" published by the licensing authority on its website on 28th January 2008(**5**).

Single set of changes

30.—(1) Unless paragraph 31 applies, the fee payable under regulation 22(1) in connection with a set of proposed changes to the labelling or the package leaflet of a medicinal product is —

(a) £524, in respect of a product which is the subject of a United Kingdom marketing authorization other than a parallel import licence; and

(b) £332, in respect of a product which is the subject of a parallel import licence.

(2) But if the proposed changes in respect of a product to which the fee in sub-paragraph (a) applies are submitted in accordance with the BROMI labels and leaflets self – certification procedure the fee payable under regulation 22(1) is £188.

(3) For the purpose of this paragraph changes are submitted in accordance with the BROMI self -certification procedure if they are of a type described in the BROMI labels and leaflets self-certification guidance and comply with the conditions set out in relation to those changes in that guidance.

More than one set of charges purposed

31.—(1) This paragraph applies where more than one set of proposed changes falling within regulation 22(1) is submitted by the same marketing authorization holder at the same time and where—

(a) the sets of proposed changes consist of identical changes to the labelling or package leaflets of products with the same active ingredient or combination of ingredients, dosage form and clinical particulars; or

(b) the sets of proposed changes consist of identical changes to different versions of the labelling or package leaflet of the same product.

(2) Where this paragraph applies, the fee payable under regulation 22(1) is —

(a) in connection with the first set of proposed changes considered by the licensing authority, the appropriate amount specified in paragraph 30; and

(b) in connection with each of the other sets of proposed changes, 50 per cent of that amount.

(**5**) 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 Market Towers, 1 Nine Elms Lane, London SW8 5NQ or by sending an email to info@mhra.gsi.gov.uk.

PART 6

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 Authorizations

Regulatory assistance

32. Unless paragraph 33 applies, the fee payable under regulation 26(1) in connection with regulatory assistance provided by the United Kingdom acting as reference Member State where an application is made to the licensing authority for the renewal of a United Kingdom marketing authorization in relation to a medicinal product which has been subject to the procedures specified in regulation 26(2), is —

(a) £9,803, if the application for renewal relates to a medicinal product which, at the time the United Kingdom marketing authorization was granted, contained a new active ingredient and that renewal is the first renewal in relation to which the United Kingdom is to provide regulatory assistance acting as reference Member State; or

(b) £756, in any other case.

Regulatory assistance – same manufacturer

33.—(1) This paragraph applies if more than one application falling within regulation 26(1) 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, therapeutic indications and Periodic Safety Update Reports, and the United Kingdom marketing authorizations for those products have the same date for renewal.

(2) The fee payable under regulation 26(1) for applications to which sub-paragraph (1) applies is—

(a) if the applications fall within paragraph 32(a)—

(i) for the first application considered by the licensing authority, the amount specified in paragraph 32(a), and

(ii) £756, for each other application;

(b) if the applications fall within sub-paragraph (1) of paragraph 32(b)—

(i) for the first application considered by the licensing authority, the amount specified in paragraph 32(b), and

(ii) £378, for each other application.