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

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

PART 1

General: interpretation and categories of applications and variations

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;

"EU marketing authorization" means—

(a) a marketing authorization; or

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

"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";

"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 33 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 of 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 Union) as an approved ingredient or additive in food or in a food product;

(b) in Part 2, paragraph 33 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 Union) 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 Union) 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 EU marketing authorization; or

(b) has an EU 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

(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;

"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.

General: categories of Applications and Variations

2.—(1) In this Schedule, references to a particular type of application, variation or variation application shall be construed in accordance with this paragraph and paragraphs 3 to 23.

(2) A reference to—

"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; and

"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.

Administrative variation application

3. An administrative variation application is 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; or

(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.

Extension application

4. An extension application is an application—

(a) for an extension of a marketing authorization within the meaning of Article 2(4) of EC Regulation No. 1234/2008; and

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

Complex application

5. A complex application is an application, other than a major application, for a marketing authorization where the application falls within one or more of the following sub-paragraphs—

(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 relation to 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 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 applicant 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 an extension application;

(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; or

(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

6. A complex registration application is 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.

Complex variation application

7. A complex variation application is 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.

Decentralised procedure application

8. A decentralised procedure application is 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.

Extended Type II Complex Variation Application

9. An Extended Type II Complex Variation Application is 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.

Major application

10. A major application is an application for a marketing authorization made to the licensing authority on the grounds that a medicinal product contains a new active ingredient.

Mutual recognition procedure incoming application

11. A mutual recognition procedure incoming application is 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 excipient variation application

12. A new excipient variation application is 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

13. A new indication variation application is 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.

Parallel Import Licence application

14.—(1) An application for a Simple Parallel Import licence means an application for a parallel import licence in respect of a proposed importation of a medicinal product ("P") which is similar to a medicinal product ("R") in respect of which a marketing authorisation has already been granted in the United Kingdom.

(2) For the purposes of sub-paragraph (1) "similar" means—

(a) the manufacturer of P and the manufacturer of R are either the same company or belong to the same group of companies or, in the case of independent companies, agreements have been concluded with the same licensor; and

(b) product P and R are manufactured according to the same formulation, using the same active ingredients, have the same pharmaceutical form and have no differences that will result in a difference in the therapeutic effect.

(3) An application for a Complex Parallel Import licence means an application for a parallel import licence which is not a Simple Parallel Import licence and the application is in respect of a medicinal product—

(a) containing a new excipient;

(b) 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;

(c) which is a controlled release preparation;

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

(e) which is 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;

(f) containing an active ingredient which, unless that active ingredient is covered by a European Pharmacopoeia certificate of suitability, is not manufactured by a manufacturer of the active ingredient which is included in the medicinal product in respect of which a marketing authorization (other than a product licence of right) has previously been granted;

(g) which is an influenza vaccine;

(h) which is to be delivered by way of a metered dose inhaler;

(i) which is in powder form and is to be delivered by inhalation;

(j) which falls within the description of the medicinal product set out in Article 10(3) of the 2001 Directive;

(k) where the sole or primary evidence for the safety and efficacy of that product consists of published scientific literature;

(l) in respect of which a marketing authorization has not been made pursuant to Article 10, 10a or 10c of the 2001 Directive by the competent authority in the Member State of exportation, and the application includes the results of pre-clinical tests or clinical trials within the meaning of Article 8(3)(i) of the 2001 Directive; or

(m) in respect of which a marketing authorization to which the first sub-paragraph of paragraph 3 of Part II of Annex I to the 2001 Directive applied in the Member State of exportation.

(4) An application for a Standard Parallel Import licence means an application for a parallel import licence which is not a Complex Parallel Import licence or a Simple Parallel Import licence.

(5) An application shall not fall within the meaning of sub-paragraph (1), (3) or (4) where the applicant and the holder of the marketing authorization in the Member State of exportation in respect of which the medicinal product in question relates are a parent undertaking and subsidiary undertaking within the meaning of section 1162 (taken together with section 1161 of, and Schedule 7 to) the Companies Act 2006(**1**).

Reclassification variation application

15. A reclassification variation application is 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 or on general sale, where previously it was available only on prescription; or

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

Reduced registration application

16.—(1) A reduced registration application category I is 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.

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

(2) A reference to a 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

17. A simple application is an application—

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

(b) 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

18. A standard application is 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

19. A 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.

Standard variation application

20. A standard variation application is 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 medicinal product

21. A standard variation application for a homoeopathic medicinal product is an application for a variation of a marketing authorization for a national homoeopathic 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 or 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 IB and Type II Applications

22.—(1) A Type IB Application is 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 2(5) of EC Regulation No. 1234/2008.

(2) A Type II Application is 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) an application for an extension of a marketing authorization within the meaning of Article 2(4) of EC Regulation No. 1234/2008.

(3) For the purposes of sub-paragraph (2)(b), a 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 2(2) of EC Regulation No. 1234/2008.

Type II Complex Variation Application

23. A Type II Complex Variation Application is 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 I to EC Regulation No. 1234/2008 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 of type II" within the meaning of Article 2(3) of EC Regulation No. 1234/2008 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) sub-paragraph (c), (e), (g), (h), (j) or (n) of the definition of complex application in paragraph 5 of this Schedule would apply where an application for a marketing authorization is made in respect of a medicinal product; or

(ii) sub-paragraph (i) of that definition would so apply and the change is not a minor variation of type IA or a minor variation of type IB within the meaning of EC Regulation No. 1234/2008.

PART 2

Capital Fees for Applications for Authorizations, Licences, Registrations and Certificates

Marketing authorizations

24.—(1) Unless paragraphs 25, 26, 28 or 29 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	£32,135	£33,709

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*
(b)	which is a mutual recognition procedure incoming application	£67,468	£70,774
(c)	which is a European reference product application	£67,468	£70,774
(d)	which is a decentralised procedure application where the United Kingdom is a concerned Member State	£96,797	£101,541
(e)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£147,479	£154,706
(f)	in any other case	£100,252	£105,146
2. Complex application			
(a)	which is a mutual recognition procedure incoming application	£18,732	£19,650
(b)	which is a European reference product application	£18,732	£19,650
(c)	which is a decentralised procedure application where the United Kingdom is a concerned Member State	£26,762	£28,073
(d)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£43,195	£45,312
(e)	in any other case	£27,716	£29,068
3. Standard application			
(a)	which is a mutual recognition procedure incoming application	£6,864	£7,200
(b)	which is a European reference product application	£6,864	£7,200
(c)	which is a decentralised procedure application where the United Kingdom is a concerned Member State	£9,812	£10,294
(d)	which is a decentralised procedure application where the United Kingdom is a reference Member State	£18,980	£19,910
(e)	in any other case	£10,162	£10,659
4. Simple application			
(a)	which is a decentralised procedure application where the United Kingdom is a concerned Member State	£2,771	£2,906

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*
(b) which is a decentralised procedure application where the United Kingdom is a reference Member State	£9,788	£10,303
(c) in any other case	£2,771	£2,906
5. Parallel import licence applications		
(a) in respect of a simple parallel import licence	*Not applicable*	£1,937
(b) in respect of a standard parallel import licence	*Not applicable*	£7,201
(c) in respect of a complex parallel import licence	*Not applicable*	£19,650
6. Change of ownership application	*Not applicable*	£478

(2) Each reference in paragraphs 25, 27 and 28 to an amount payable under paragraph 24 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

25.—(1) Unless paragraph 27 applies, where an application, other than a major application, includes a reclassification element and—

(a) the reclassification falls within the category of application described in paragraph 15(a), an amount of—

(i) £12,961, if the application is an eCTD format application; or

(ii) £13,595, if the application is not an eCTD format application,

is payable in addition to the amount payable under paragraph 24 in respect of that application; or

(b) the reclassification falls within the category of application described in paragraph 15(b), an amount of—

(i) £8,822, if the application is an eCTD format application; or

(ii) £9,252, if the application is not an eCTD format application,

is payable in addition to the amount payable under paragraph 24 in respect of that application.

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

(a) in the case of an application falling within the category described in paragraph 15(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) in the case of an application falling within the category described in paragraph 15(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 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 application is made.

Fees where person holds clinical trial certificate

26. 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

27.—(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;

(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 24 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 24;

(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 24;

(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 24 and in respect of any other such application by that secondary applicant, the amount payable in respect of a standard application under paragraph 24.

(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 24;

(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 24.

Application for multiple authorizations

28.—(1) Unless sub-paragraph (2), (3) or (4) applies, 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 24 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 24 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 24;

(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 24; 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 24.

(3) If the application is a complex application, the amount payable is the amount payable in respect of a complex application under paragraph 24 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 24;

(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 24; 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 24.

(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 in respect of the relevant category of reclassification variation application under paragraph 25(1); and

(b) in respect of each other marketing authorization applied for that includes a reclassification element, £832, except in the case of an eCTD format application in which case the additional amount payable is £794.

(5) For the purposes of sub-paragraph (4), a "reclassification element" has the meaning given in paragraph 25(2).

Authorisation for a national homoeopathic product

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

(a) the applicant holds a certificate of registration or a homoeopathic marketing authorization; or

(b) 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.

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

(3) 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.

(4) 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.

Fees for homoeopathic marketing authorization applications

Column 1 *Description of application*	*Column 2* *Fee for applications in respect of products prepared from not more than 5 homoeopathic stocks*	*Column 3* *Fee 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	£558	£791
2. An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£874	£1,096
3. Any other application	£1,176	£1,418

(5) Each reference in sub-paragraphs (6) to (8) to an amount payable under sub-paragraph (3) or (4) in respect of an application refers to the amount payable under that sub-paragraph in respect of an application of the kind in question.

(6) 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 £2,328 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

(7) Where an application relates to a national homoeopathic product which contains one or more new excipients, an amount of £7,766 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

(8) Where an application relates to a national homoeopathic product which contains one or more TSE risk ingredients from a new source or TSE risk excipients from a new source, an amount of £686 is payable in addition to the amount payable under sub-paragraph (3) or (4) in respect of that application.

Manufacturer's licences and authorisations

30.—(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) £178, in a case to which sub-paragraph (2) applies;

(b) £335, in the case of a change of ownership application; and

(c) £3,057, 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(**2**) applies.

Wholesale dealer's licences

31.—(1) Unless sub-paragraph (2) or (6) applies, the fee payable under regulation 12(1)(a) in connection with an application for a wholesale dealer's licence is £1,754.

(2) Where this sub-paragraph applies, the fee payable under regulation 12(1)(a) is £751.

(3) Subject to sub-paragraph (5), 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% 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(**3**).

(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) 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% 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 that applicant so informs the licensing authority when the application is made.

(6) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £388.

Clinical trial authorisations

32.—(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

(**2**) S.I. 1971/1450 to which there are no relevant amendments.
(**3**) Section 51(1) has been amended by S.I. 2006/2407.

in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

Fees for clinical trial authorisation applications

Column 1 *Kind of clinical trial*	*Column 2* *Fee payable*
Phase I trial	£2,255
Phase II or Phase III trial where the medicinal product being tested is unknown to the licensing authority	£4,244
Phase II or Phase III trial where the product being tested is known to the licensing authority	£3,448
Phase IV trial	£265

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

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

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

(i) another pharmaceutical form or strength of that product has an EU 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 EU 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(**4**).

(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 £265.

(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,

(**4**) OJNo. L 121, 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.

the fee payable in connection with that application is £265.

Traditional herbal registrations

33.—(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—

Fee for application for traditional herbal registration

Column 1 *Kind of application*		*Column 2* *Fee payable*
1. Complex registration application		
(a)	in respect of a medicinal product containing a single active ingredient	£5,237
(b)	in any other case	£7,857
2. Standard registration application		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£2,619
(b)	in any other case	£3,928
3. Reduced registration application category II		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£873
(b)	in any other case	£1,310
4. Reduced registration application category I		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£583
(b)	in any other case	£873
5. Change of ownership application		£478

(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) £1,164, 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; or

(b) £2,328, 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 £7,767 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 £690 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 £2,328 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

Outgoing mutual recognition applications

34.—(1) The fee payable under regulation 16 (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 another EEA State or in other EEA States) is the fee specified in sub-paragraphs (2) to (5).

(2) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom (the application relating to that authorization is referred to in this paragraph as the "original application") and the original application had been a major application or would fall within the meaning of a major application, in respect of—

(a) the first application for regulatory assistance ("the first application"), the fee is £44,934;

(b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;

(c) each subsequent application for regulatory assistance ("subsequent application"), the fee is £29,516; and

(d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(3) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a complex application or would fall within the meaning of a complex application, in respect of—

(a) the first application for regulatory assistance ("the first application"), the fee is £11,623;

(b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;

(c) each subsequent application for regulatory assistance ("subsequent application"), the fee is £7,709; and

(d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(4) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a standard application or would fall within the meaning of a standard application, in respect of—

(a) the first application for regulatory assistance ("the first application"), the fee is £4,628;

(b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;

(c) each subsequent application for regulatory assistance ("subsequent application"), the fee is £3,855; and

(d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(5) In the case where the application to the licensing authority relates to a medicinal product for which a marketing authorization was granted in the United Kingdom and the original application had been a simple application or would fall within the meaning of a simple application, in respect of—

(a) the first application for regulatory assistance ("the first application"), the fee is £2,769;

(b) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as the first application, the fee is £2,769;

(c) each subsequent application for regulatory assistance ("subsequent application"), the fee is £2,769; and

(d) any other application for regulatory assistance meeting the condition in sub-paragraph (6) and made at the same time as any subsequent application, the fee is £2,769.

(6) The condition referred to in sub-paragraphs (2) to (5) is that all applications fall within the meaning given to a set of applications in regulation 15.

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—

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

(b) if the fee is not in an eCTD format application, the fee specified in the corresponding entry in column 3 of that 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(**5**), 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(**6**); and

(**5**) See Article 1 of the Regulation.
(**6**) 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.

(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 construed accordingly.

Table 1

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

Column 1 *Kind of variation*	*Column 2* *Fee payable if in eCTD format*	*Column 3* *Fee payable for application not in eCTD format*
1. Application for a single kind variation		
(a) Type IB Application where—		
(i) the UK is a concerned Member State	£300	£318
(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£594	£622
(b) Type II Application where—		
(i) the UK is a concerned Member State	£794	£832
(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£962	£1,008
(c) Type II Complex Variation Application where—		
(i) the UK is a concerned Member State	£8,981	£9,420
(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£15,571	£16,332
(d) Extended Type II Complex Variation Application where—		
(i) the UK is a concerned Member State	£27,716	£29,068
(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£38,744	£40,634
2. Applications for a Group		
(a) Minor Variation (Type IB) Group Application where—		
(i) the UK is a concerned Member State	£672	£708

Column 1 *Kind of variation*			*Column 2* *Fee payable if in eCTD format*	*Column 3* *Fee payable for application not in eCTD format*
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£1,324	£1,394
(b)	Major Variation (Type II) Group Application where—			
	(i)	the UK is a concerned Member State	£1,786	£1,880
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£2,158	£2,274
(c)	Major Variation (Type II) Complex Group Application where—			
	(i)	the UK is a concerned Member State	£9,738	£10,252
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£16,465	£17,332
(d)	Major Variation (Type II) Extended Complex Group Application where—			
	(i)	the UK is a concerned Member State	£28,401	£29,896
	(ii)	the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£39,693	£41,612

Table 2

Fees for UK national variation applications

Column 1 *Kind of national variation*	*Column 2* *Fee payable if in eCTD format*	*Column 3* *Fee payable for application not in eCTD format*
1. National Type 1B Application	£300	£318
2. National Type II Application	£794	£832
3. National Type II Complex Variation Application	£8,981	£9,420
4. National Type II Extended Complex Variation Application	£27,716	£29,068
5. National Type IB Minor Variation Group Application	£672	£708

Column 1 *Kind of national variation*	*Column 2* *Fee payable if in eCTD format*	*Column 3* *Fee payable for application not in eCTD format*
6. National Type II Major Variation Group Application	£1,786	£1,880
7. National Type II Major Variation Complex Group Application	£9,738	£10,252
8. National Type II Major Variation Extended Complex Group Application	£28,401	£29,896

Table 3

Fees for reclassification variation applications

Column 1 *Kind of reclassification variation*	*Column 2* *Fee payable if in eCTD format*	*Column 3* *Fee payable for application not in eCTD format*
Application falling within the category described in—		
(a) paragraph 15(a)	£12,961	£13,595
(b) paragraph 15(b)	£8,822	£9,252

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 £832, unless the application is an eCTD format application, in which case the fee payable under regulation 18(1) 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 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; 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, is £832, unless the application is in an eCTD format application, in which case the fee payable is £794; and

(iii) in connection with each other application to which paragraph 37 does apply, is £416, unless the application is in an eCTD format application, in which case 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, is £416, unless the application is in an eCTD format application, in which case the fee payable is £397.

PART 5

Capital Fees for Assessment of Labels and Leaflets

A set of changes

49.—(1) Unless paragraph 50 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) £559, in respect of a product which is the subject of a United Kingdom marketing authorization (other than a parallel import licence); and

(b) £354, in respect of a product which is the subject of a parallel import licence.

(2) If the proposed changes in respect of a product to which the fee in sub-paragraph (1)(a) applies are submitted in accordance with the National Guidance on labels and leaflets self-certification, the fee payable under regulation 22(1) is £201.

(3) For the purpose of this paragraph—

(a) changes are submitted in accordance with the National Guidance on labels and leaflets self-certification if they are of a type described in the National Guidance on labelling and patient information leaflets for self-certification and comply with the conditions set out in relation to those changes in that Guidance; and

(b) the "National Guidance on labelling and patient information leaflets for self-certification" means the documents entitled "Guidance on changes to labelling and patient information for self-certification" and "Guidance on changes to labelling for self certification – compliance with article 56(a) – inclusion of Braille on the labelling" published by the licensing authority and available on its website on 9th November 2009(**7**).

More than one set of charges proposed

50.—(1) In this paragraph, "clinical particulars" 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.

(2) 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.

(3) 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 49; and

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

(**7**) Copies of the documents 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

51. Unless paragraph 52 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) £10,465, 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) £807, in any other case.

Regulatory assistance – same manufacturer

52.—(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 51(a)—

(i) £10,465 for the first application considered by the licensing authority; and

(ii) £807 for each other application;

(b) if the applications fall within paragraph 51(b)—

(i) £807 for the first application considered by the licensing authority; and

(ii) £405 for each other application.