SCHEDULE 1

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

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
(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

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 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
(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

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*
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(**1**) 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—

(**1**) S.I. 1971/1450 to which there are no relevant amendments.

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

(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(**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 £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,

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

(**3**) 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.

Column 1 *Kind of application*		*Column 2* *Fee payable*
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.