SCHEDULES

SCHEDULE 2

Capital fees for applications for, and variations to, marketing authorisations, licences, registrations and certificates

PART 2

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

Marketing authorisations

24.—(1) Unless sub-paragraphs (2) or (4) or paragraphs 25, 26, 28 or 29 apply, the fee payable under regulation 12(1)(a) in connection with an application for a marketing authorisation of a kind described in column 1 of the following table is the fee specified in the corresponding entry in column 2 of that table.

(2) This paragraph applies—

(a) to a complex application for a marketing authorisation of a kind described in item 2 in column 1 of the following table; and

(b) where the application only concerns a new source or supply of a substance listed in Part 7 of this Schedule.

(3) If sub-paragraph (2) applies the appropriate fee is the amount specified for an application of the same type under item 3 of the following table.

(4) This paragraph applies—

(a) to a complex application for a parallel import licence of a kind described in item 5(c) in column 1 of the following table; and

(b) where the application only concerns a new source or supply of a relevant substance listed in Part 7 of this Schedule.

(5) If sub-paragraph (4) applies the appropriate fee is the amount specified for item 5(b) in the following table.

Fees for marketing authorisation applications

Column 1		*Column 2*
Kind of application		*Fee payable*
1. Major application		
(a)	in respect of an application relating to an orphan medicinal product to which point 6 of Part II of Annex 1 to the 2001 Directive applies	£29,732
(b)	which is a mutual recognition procedure incoming application	£62,421

Column 1		*Column 2*
Kind of application		*Fee payable*
(c)	which is a European reference product application	£62,421
(d)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£89,556
(e)	which is a decentralised procedure application where the United Kingdom is a reference member State	£121,664
(f)	in any other case	£92,753
2. Complex application		
(a)	which is a mutual recognition procedure incoming application	£17,330
(b)	which is a European reference product application	£17,330
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£24,760
(d)	which is a decentralised procedure application where the United Kingdom is a reference member State	£35,634
(e)	in any other case	£25,643
3. Standard application		
(a)	which is a mutual recognition procedure incoming application	£6,350
(b)	which is a European reference product application	£6,350
(c)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£9,078
(d)	which is a decentralised procedure application where the United Kingdom is a reference member State	£15,659
(e)	in any other case	£9,402
4. Simple application		
(a)	which is a decentralised procedure application where the United Kingdom is a concerned member State	£2,564
(b)	which is a decentralised procedure application where the United Kingdom is a reference member State	£8,105
(c)	in any other case	£2,564
5. Parallel import licence applications		
(a)	in respect of a simple parallel import licence	£1,792
(b)	in respect of a standard parallel import licence	£6,663
(c)	in respect of a complex parallel import licence	£18,180
6. Change of ownership application		£442

(6) 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 this 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 £11,992 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 £8,162 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 authorisation or a European Union marketing authorisation 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 authorisation 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 authorisations 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 the Commission on Human Medicines, the Herbal Medicines Advisory Committee or the Advisory Board on the Registration of Homoeopathic Products;

(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 authorisations 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 authorisation 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 authorisation 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 authorisation 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 authorisations 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 authorisation 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 authorisation 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 authorisation 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 authorisation 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 applicant 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 authorisations

28.—(1) Unless sub-paragraph (2), (3) or (4) applies, where an application for a marketing authorisation is for more than one such authorisation 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 total of the amounts payable under paragraph 24 in respect of a separate application for each such authorisation.

(2) If the application is a major application, the amount payable is the amount payable in respect of a major application under paragraph 24 and—

(a) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form with a different route of administration, the amount payable in respect of a complex application under paragraph 24;

(b) in respect of each additional marketing authorisation applied for which relates to a medicinal product of a different dosage form but with the same route of administration, the amount payable in respect of a standard application under paragraph 24; and

(c) in respect of each additional marketing authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, 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 authorisation 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 authorisation 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 authorisation applied for which relates to a medicinal product of the same dosage form but of a different strength of active ingredient or different combination of active ingredients, the amount payable in respect of a standard application under paragraph 24.

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

(a) in respect of the first marketing authorisation 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 authorisation applied for that includes a reclassification element, £734.

(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;

"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.

(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 authorisation 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 authorisation 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 authorisation 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	£517	£732
2. An application in respect of a product which is either— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£808	£1,014
3. Any other application	£1,088	£1,312

(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 authorisation (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 £2,154 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 £7,185 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 £635 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) £183 in a case to which sub-paragraph (2) applies;

(b) £344 in the case of a change of ownership application; and

(c) £3,143 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 regulation 169 (mixing of general sale medicinal products) of the Human Medicines Regulations applies.

Wholesale dealer's licences

31.—(1) Unless sub-paragraph (2) or (5) applies, the fee payable under regulation 12(1)(a) in connection with an application for a wholesale dealer's licence is £1,803.

(2) Where this sub-paragraph applies, the fee payable under regulation 12(1)(a) is £902.

(3) Subject to sub-paragraph (4), 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 classified as subject to general sale under regulation 5(1) (classification of medicinal products) or paragraph 3(5) of Schedule 32 (transitional provisions and savings: product licences of right) to the Human Medicines Regulations.

(4) 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.

(5) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

Broker's registrations

32.—(1) The fee payable under regulation 12(1)(a) in connection with an application for a broker's registration is £1,803.

(2) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

Active substance registrations

33.—(1) The fee payable under regulation 12(1)(a) in connection with an application for an active substance registration is—

(a) £3,143 where the application includes the manufacture of active substances; or

(b) £1,803 where the application only concerns the importation or distribution of active substances.

(2) The fee payable under regulation 12(1)(a) in connection with a change of ownership application is £399.

Clinical trial authorisations

34. The fee payable under regulation 12(1)(a) in connection with an application for a clinical trial authorisation is—

(a) £3,060, where the application is for a product that is not marketed; or

(b) £225, where the application is for a product that is marketed.

Traditional herbal registrations

35.—(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	£4,846
(b)	in any other case	£7,269
2. Standard registration application		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£2,423
(b)	in any other case	£3,634
3. Reduced registration application category II		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£807
(b)	in any other case	£1,212
4. Reduced registration application category I		
(a)	in respect of a medicinal product containing 3 or fewer active ingredients	£539
(b)	in any other case	£807
5. Change of ownership application		£442

(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) £1,077, 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) £2,154, 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 £7,186 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 £638 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 £2,154 is payable in addition to the amount payable under sub-paragraph (1) in respect of that application.

Online sellers of medicines

36. The fee payable under regulation 13 in connection with an application to be included on the list of online sellers of medicines is £100.