SCHEDULE 1 Regulations 3(a), 5(a) and 8(a)

CAPITAL FEES FOR APPLICATIONS, VARIATIONS AND RENEWALS OF LICENCES

PART I

INTERPRETATION

In this Schedule—

"active ingredient" means the ingredient of a medicinal product in respect of which efficacy is claimed;

"complex application" means an application, other than a major application, for a product licence or, as the case may be, for a variation to a product licence where the application—

(a) is subject to the procedure laid down in Article 17 of Council Directive 81/851/EEC(**1**) (notification to five or more Member States);

(b) relates to a medicinal product which is intended to be used in accordance with an indication for use in respect of a different species of animal or as treatment for a new medicinal purpose;

(c) relates to a medicinal product containing a new combination of active ingredients which have not previously been included in that combination in a medicinal product in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(d) relates to a medicinal product containing a new adjuvant or a new excipient;

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

(f) 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 product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(g) 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 product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(h) relates to a biological medicinal product containing an active ingredient, the manufacture of which involves a growth substrate 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 product licence has previously been granted in the United Kingdom;

(i) relates to a medicinal product which is a controlled release preparation and a product licence for animal use (other than a product licence of right) for such a preparation

(**1**) OJNo. L317, 28.9.81, p.1.

constituting the same active ingredient as the product in question has not previously been granted in the United Kingdom;

(j) 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 ingredient as the product in question and in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(k) names as manufacturer of the active ingredient of the medicinal product in question a different manufacturer from the manufacturer of the active ingredient of any medicinal product which contains the same active ingredient as the medicinal product in question and in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(l) relates to a biological medicinal product containing an active ingredient derived from a strain of micro-organism 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 product licence has previously been granted in the United Kingdom;

"major application" means an application for a product licence in respect of a medicinal product containing a new active ingredient;

"new active ingredient" means—

(a) an active ingredient that has not previously been included as an active ingredient in a medicinal product in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(b) an active ingredient in a medicinal product derived from genetically engineered micro-organisms, recombinant DNA technology or monoclonal antibodies; or

(c) in the case of a biological medicinal product, a vaccine of a particular micro-organism whether in a live or inactivated form, but this does not include a vaccine of a particular micro-organism which is derived from a strain of micro-organism which is antigenetically similar to that used in the manufacture of the active ingredient of a medicinal product in respect of which a product licence (not being a product licence of right) has previously been granted in the United Kingdom;

"new excipient" means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product—

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

(b) in respect of which a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom 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) as an approved ingredient or additive—

(i) in food or food products; or

(ii) in animal feedingstuffs where that product is intended for administration after being incorporated in the feedingstuff;

"simple application" means an application for a product licence when the application—

(a) is made by reference to an application for a particular product ("the existing product") in respect of which a product licence for animal use (other than a product licence of right) has previously been granted;

(b) is made by permission of the licence holder for the existing product;

(c) relates to a product which is in all the following respects the same as the existing product—

(i) it contains the same combination of active ingredients;

(ii) it is intended to be used in accordance with the same indications;

(iii) it is intended to be administered by the same route of administration;

(iv) the manufacturer named in the application is the same as the manufacturer of the existing product;

(v) the method of manufacture is the same;

(vi) in the case of a sterile product the method of sterilisation is the same and the container which is directly in contact with the product is made from the same material;

"standard application" means—

(a) any application in respect of a medicinal product for animal use specified in Annex 1 of Council directive 70/524/EEC(**2**) or made pursuant to the Medicines (Exportation of Specified Veterinary Products) Order 1971(**3**), which is not a simple application;

(b) any other application which is not a major, complex or simple application.

PART II

CAPITAL FEES FOR APPLICATIONS FOR LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraph 2, the fee payable under regulation 3(a) in connection with an application for a product licence of a kind described in column 1 of the following Table shall be the fee specified in the corresponding entry in column 2 of that Table:

Column 1 Kind of application	Column 2 Appropriate fee
1. Major application	**1.** £12,600
2. Complex application	**2.** £ 7,350
3. Standard application	**3.** £ 3,150
4. Simple application	**4.** £ 1,050
5. Emergency vaccine application	**5.** £ 30

2. Where—

(a) a major or a complex application is made by a person who is already the holder of an animal test certificate, in respect of a medicinal product containing the same active ingredient as the medicinal product in respect of which the product licence is applied for, or

(**2**) OJ No. L270, 23.11.70, p.1, as amended by Council Directive 84/587/EEC, OJ No. L319, 8.12.84, p.13.
(**3**) S.I.1971/1309.

(b) a major or a complex application is made by a person who is already the holder of a product licence (export only), relating to the same medicinal product as the product licence is applied for,

the fee payable under regulation 3(a) in connection with that application shall be reduced by the amount of the fee paid in connection with the application for that certificate or licence.

3.—(1) Subject to sub-paragraphs (2) and (3), where an application for a product licence consists of an application for more than one such licence each relating to a product containing the same active ingredient or combination of ingredients, the fee payable under regulation 3(a) shall be of an amount equal to the aggregate of the amounts payable under paragraph 1 in respect of separate applications for each such licence.

(2) If the application is a major application, the amount payable shall be the amount payable in respect of a major application under paragraph 1 plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1; and

(b) in respect of each additional product licence 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 1.

(3) If the application is a complex application, the amount payable shall be the amount payable in respect of a complex application tinder paragraph 1 plus—

(a) in respect of each additional product licence applied for which relates to a medicinal product of a different dosage form, the amount payable in respect of a complex application under paragraph 1; and

(b) in respect of each additional product licence 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 1.

Animal test certificates

4. The fee payable under regulation 3(a) in connection with an application for an animal test certificate shall be £4,200.

Manufacturers' licences

5.—(1) The fee payable under regulation 3(a) in connection with an application for a manufacturer's licence shall be—

(a) in at case to which sub-paragraph (2) below applies, £85; or

(b) in any other case £1,825; and

(c) in either case, if appropriate, a fee calculated in accordance with Schedule 2 in respect of any inspection made in connection with that application.

(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—

(a) medicinal products the sale or supply of which do not require a product licence and to which Article 2(2)(i)(e) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**4**) applies; or

(b) emergency vaccines.

Wholesale dealers' licences

6. The fee payable under regulation 3(a) in connection with an application for a wholesale dealer's licence shall be £1,200.

Animal test (confirmation of exemption) certificate

7. The fee payable under regulation 3(a) in connection with an application for an animal test (confirmation of exemption) certificate under the Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986(**5**) shall be—

(a)	(a) in respect of new molecules— (i) in food producing animals	£2,500
(ii)	in non-food producing animals	£1,250
(b)	(b) in respect of non-licensed inactivated vaccines	£2,500
(c)	(c) in respect of licensed live vaccines	£1,500
(d)	(d) in respect of licensed inactivated vaccines	£1,500
(e)	(e) any other application	£ 500

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

Product licences

1. Subject to paragraph 5, the fee payable under regulation 5(a) in connection with an application for variation of a product licence—

(a) in the case of a complex application, shall be £1,075; and

(b) in any other case—

(i) requiring veterinary, scientific or pharmaceutical assessment—

(aa) for a variation, shall be £325;

(bb) for any other consequential variation to other licences, in identical terms shall be £110;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £110 in respect of each variation.

(**4**) S.I. 1971/1450; the relevant amending instrument is S.I. 1972/1200.
(**5**) S.I. 1986/1180, amended by S.I. 1991/633.

Manufacturers' licences

2. Subject to paragraph 5, the fee payable under regulation 5(a) in connection with an application for variation of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence referred to in paragraph 4(2) of Part II of this Schedule, £90;

(b) in the case of a licence relating to an emergency vaccine, £85;

(c) in any other case, £325.

Wholesale dealers' licences

3. Subject to paragraph 5, the fee payable under regulation 5(a) in connection with an application for variation of a wholesale dealer's licence shall be £325.

Animal test certificates

4. Subject to paragraph 5, the fee payable under regulation 5(a) in connection with an application for variation of—

(a) an animal test certificate—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £315;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £105; or

(b) an animal test (confirmation of exemption) certificate—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall he £300;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £85.

Other variations

5. The fee payable under regulation 5(a) in connection with an application for variation of—

(a) a product licence, animal test certificate or animal test (confirmation of exemption) certificate where the variation applied for consists of a change to the licence or certificate not requiring veterinary, scientific or pharmaceutical assessment, shall be £110;

(b) a manufacturer's licence or a wholesale dealer's licence where the variation applied for consists of a change to the licence not requiring veterinary, scientific or pharmaceutical assessment, shall be £90;

(c) any licence or certificate issued under Part II of the Act where the variation applied for involves the reissue of the licence or certificate in the new name of the company, shall be £110;

(d) any licence relating solely to an emergency vaccine, £30.

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES

Product licences

1. The fee payable under regulation 8(a) in connection with an application for renewal of a product licence shall be £420, and, in the case of a licence relating solely to an emergency vaccine, £30.

Manufacturers' licences

2. The fee payable under regulation 8(a) in connection with an application for renewal of a manufacturer's licence shall be—

(a) in the case of a manufacturer's licence referred to in paragraph 5(2) of Part II of this Schedule, £85;

(b) in any other case, £925.

Wholesale dealers' licences

3. The fee payable under regulation 8(a) in connection with an application for renewal of a wholesale dealer's licence shall be £600.

Animal test certificates

4. The fee payable under regulation 8(a) in connection with an application for renewal of an animal test certificate shall be £500.