SCHEDULE 1 Regulations 3 and 9

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 animal test certificate or, as the case may be, for a variation to a product licence or animal test certificate 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, 6.11.81, 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 cointaining 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) the formulation is identical;

(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**) which is not a simple application;

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

PART II

FEES FOR APPLICATIONS FOR LICENCES AND CERTIFICATES

Product licences

1. Subject to paragraph 2, the fee for an application for a product licence shall be in accordance with the following Table:

Kind of application	Fee
Major application	£13,800
Complex application	£8,000
Standard application	£3,450
Simple application	£1,150
Emergency vaccine application	£40

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

(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 applied for,

the fee shall be reduced by the amount of the fee paid in connection with the application for that certificate or licence.

(**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.—(1) Subject to sub-paragraphs (2) and (3) below, 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 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 fee 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 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 standard 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 simple application under paragraph 1.

Animal test certificates

4. The fee for an application for an animal test certificate shall be £4,400.

Manufacturers' licences

5.—(1) The fee for an application for a manufacturer's licence shall be—

(a) in a case to which sub-paragraph (2) below applies, £90; or

(b) in any other case £1,900; 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) Sub-paragraph (1)(a) above 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(**3**) applies; or

(b) emergency vaccines.

Wholesale dealers' licences

6.—(1) Subject to sub-paragraph (2) below the fee for an application for a wholesale dealer's licence shall be £1,300.

(**3**) S.I.1971/1450; the relevant amending instrument is S.I. 1972/1200.

(2) In the case of a wholesale dealer who has a turnover in respect of veterinary medicinal products—

(a) of less than £30,000; or

(b) of less than 15% of his total turnover

the fee payable in connection with an application for a wholesale dealer's licence, if accompanied (in either case) by a declaration certifying the low turnover, shall be £440.

(3) For the purposes of paragraph 6(2), "turnover" means the gross value of all veterinary medicinal products sold by way of wholesale dealing by the applicant in the United Kingdom during the previous calendar year. Medicinal products sold by way of wholesale dealing by the licence holder shall comprise only those products in respect of which a licence is held during the whole or part of that calendar year.

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

Product licences

1.—(1) The fee for a complex application for variation of a product licence shall be £1,100.

(2) The fee for an application for the variation of a product licence other than a complex application shall be in accordance with the following Table:

Kind of application	Fee payable
Variation requiring veterinary, scientific or pharmaceutical assessment	£340 for the first variation plus £140 for each additional consequential variation to other licences in identical terms
Variation not requiring veterinary, scientific or pharmaceutical assessment	£140
Variation involving the re-issue of the licence in the new name of the company	£140
Variation where the product licence relates solely to an emergency vaccine	£40

Manufacturers' licences

2. The fee for an application for variation of a manufacturer's licence—

(a) in the case of a manufacturer's licence referred to in paragraph 5(2) of Part II of this Schedule, shall be £90;

(b) in any other case—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £330;

(ii) not requiring veterinary, scientific or pharmaceutical assessment, shall be £110.

Wholesale dealers' licences

3. The fee for an application for variation of a wholesale dealer's licence—

(a) requiring veterinary, scientific or pharmaceutical assessment, shall be £330;

(b) not requiring veterinary, scientific or pharmaceutical assessment, shall be £110.

Animal test certificates

4. The fee for an application for variation of an animal test certificate shall be in accordance with the following Table:

Kind of application	Fee payable
Complex application	£1,150
Non-complex application requiring veterinary, scientific or pharmaceutical assessment	£330
Non-complex application not requiring veterinary, scientific or pharmaceutical assessment	£110
Application for the re-issue of a certificate in the new name of the company	£110

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES

Product licences

1. The fee for an application for renewal of a product licence shall be £525, and, in the case of a licence relating solely to an emergency vaccine, £40.

Manufacturers' licences

2. The fee for a manufacturer’s licence referred to in paragraph 5(2) of Part II of this Schedule, shall be £100.

Animal test certificates

3. The fee for an application for renewal of an animal test certificate shall be £525.