SCHEDULE 1 **Regulations 2(4), 3, 4, 5, 8 and 12**

FEES RELATING TO APPLICATIONS FOR THE GRANT, VARIATION AND RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

PART I

INTERPRETATION

In this Schedule, unless the context requires otherwise–

"abridged standard application" means an application for a marketing authorisation which, by virtue of regulation 4(8) of the 1994 Regulations, need not be accompanied by the results of tests and trials of the type specified in Article 5.10 of Directive 81/851/EEC but does not include a simple application or an emergency vaccine application;

"active ingredient" means the ingredient of a product in respect of which efficacy is claimed in an application to which this Schedule relates;

"application for a type A marketing authorisation" means an application for a marketing authorisation to which regulation 5(a) of the 1994 Regulations applies;

"application for a type B marketing authorisation" means an application for a marketing authorisation to which regulation 5(b) of the 1994 Regulations applies;

"Article 15.2 marketing authorisation" means a marketing authorisation of the type specified in Article 15.2 of Directive 81/851/EEC;

"biological product" includes an antigen, toxin, antitoxin, toxoid, serum, antiserum or vaccine or a fraction of any such product;

"Category I application" means an application for assistance in connection with a mutual recognition application other than a Category II or III application;

"Category II application" means an application, other than a Category III application, for assistance in connection with a mutual recognition application relating to a marketing authorisation granted in respect of a Veterinary Medicinal Product only intended for administration to animals whose flesh or products are not intended for human consumption;

"Category III application" means an application for assistance in connection with a mutual recognition application relating to a marketing authorisation granted in respect of an immunological Veterinary Medicinal Product;

"complex application" means an application for, or for a variation of, a marketing authorisation or product licence where the application–

(a) relates to a product which is intended to be used–

(i) in accordance with an indication for use in respect of a species of animal, or

(ii) as a treatment for a medicinal purpose,

for which it has not previously been used;

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

(c) relates to a product containing a new excipient;

(d) relates to a product which is intended to be administered by a route of administration different from that used in the administration of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(e) relates to a sterile product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(f) relates to a product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(g) relates to a biological 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 product–

(i) which contains the same active ingredient as the product in question and

(ii) in respect of which a marketing authorisation or product licence has previously been granted in the United Kingdom;

(h) relates to a product which is a controlled release preparation in circumstances where a marketing authorisation or product licence for animal use (other than a product licence of right) for such a preparation constituting the same active ingredient as the product in question has not previously been granted in the United Kingdom;

(i) relates to a sterile product (the container of which is directly in contact with the product) which is made from a material different from that used for the container of any product–

(i) which contains the same ingredient as the product in question and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(j) names as manufacturer of the active ingredient of the product in question a manufacturer different from the manufacturer of the active ingredient of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(k) relates to a biological 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 product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence has previously been granted in the United Kingdom, but does not include a major application or an emergency vaccine application;

"emergency vaccine" means a vaccine manufactured or assembled only from material obtained from the particular animal, flock or herd intended to be vaccinated in circumstances in which no other suitable authorised or licensed vaccines are readily available for such use;

"emergency vaccine application" means an application, limited to use of an emergency vaccine, for a marketing authorisation or product licence;

"excipient", in relation to an immunological Veterinary Medicinal Product, includes an adjuvant;

"food-producing animals" means animals whose flesh or products are intended for human consumption;

"immunological Veterinary Medicinal Product" has the same meaning as in Directive 90/677/EEC;

"individual variation" means, in relation to an application to vary (or renew with variations)–

(a) a mutually recognised marketing authorisation, a variation covered by any single numbered paragraph of Annex I to Regulation (EC) No. 541/95; and

(b) any other authorisation or licence or certificate, any element in the application which calls for a separate assessment in order to reach a decision whether the application should be granted; "marketing authorisation (parallel import)" means a marketing authorisation granted by the Ministers in respect of a Veterinary Medicinal Product–

(c) which is imported into the United Kingdom from an EEA State,

(d) for which there has been granted a marketing authorisation by an EEA State, and

(e) which has no therapeutic effect different from that of a Veterinary Medicinal Product for which a marketing authorisation has already been granted in the United Kingdom;

"major application" means an application for a marketing authorisation or product licence in respect of a product containing a new active ingredient but does not include an emergency vaccine application;

"member State" means a member State other than the United Kingdom;

"mutually recognised marketing authorisation" means a marketing authorisation which has been mutually recognised by a member State;

"new active ingredient" means–

(a) an active ingredient that has not previously been included as an active ingredient in a product in respect of which a marketing authorisation or 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 product where the product is derived from genetically engineered micro-organisms, recombinant DNA technology or monoclonal antibodies; or

(c) in the case of a biological product, a vaccine of a particular micro-organism whether in a live or inactivated form, other than 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 product in respect of which a marketing authorisation or product licence (not being a product licence of right) has previously been granted in the United Kingdom;

"new excipient", in relation to a product containing it, means any ingredient which–

(a) is not an active ingredient,

(b) has not previously been included in a product of a different description–

(i) which is intended to be administered by the same route of administration as that of the product containing it; and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted, and

(c) if the product containing it is intended to be administered orally, is not specified in any Act or subordinate legislation as able to be used lawfully as an ingredient of or additive for–

(i) food for human consumption in any event; or

(ii) animal feedingstuffs, in any case where the product containing it is intended for administration after being incorporated in an animal feedingstuff;

"Reference Member State" has the meaning given by Article 2.2 of Regulation (EC) No. 541/95;

"simple application" means an application for a marketing authorisation or 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 marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted;

(b) is made with the permission of the marketing authorisation or licence holder for the existing product; and

(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; and

(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;

but does not include an emergency vaccine application.

"standard application" means an application which is not a major, complex, abridged standard or simple application;

"Type I variation–Administrative" means a variation of a type listed in variations 2 and 3 of Annex I to Regulation (EC) No. 541/95;

"Type I variation–Scientific" means a variation of a type listed in variations 1 and 4 to 33 of Annex 1 to Regulation (EC) No. 541/95;

"Type I variation, Scientific–Type II procedure" means a variation within the derogation, insofar as it relates to products falling within the scope of Directive 90/677/EEC, in introductory statement A of Annex 1 to Regulation (EC) No. 541/95; and

"Type II variation" means a variation of the type referred to in Article 3.1(b) of Regulation (EC) No. 541/95.

PART II

FEES RELATING TO APPLICATIONS FOR THE GRANT OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations and product licences

1. Subject to paragraphs 2, 3, 4 and 5–

(a) the fee for an application for a type A marketing authorisation of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (2) of that Table;

(b) the fee for an application for a type B marketing authorisation of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (3) of that Table; and

(c) the fee for an application for a product licence of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (4) of that Table.

Table A

Column (1) *Kind of application*	*Column (2)* *Fee for an application for a type A marketing authorisation*	*Column (3)* *Fee for an application for a type B marketing authorisation*	*Column (4)* *Fee for an application for a product licence*
Major application	£18,120	£10,000	£18,120
Complex application	£10,515	£6,000	£10,515
Standard application	£4,540	£3,000	£4,540
Abridged standard application	£3,545	—	—
Simple application	£1,260	£800	£1,260
Emergency vaccine application	£40	—	£40

2. The fee for an application for an Article 15.2 marketing authorisation of a kind described in an entry in column (1) of Table B is the fee specified in the corresponding entry in column (2) of that Table.

Table B

Column (1) *Kind of application*	*Column (2)* *Fee for an application for an Article 15.2 marketing authorisation*
Major application	£10,515
Complex application	£4,540

3. Where an application for a marketing authorisation is made by a person who is already the holder of an Article 15.2 marketing authorisation relating to the same Veterinary Medicinal Product as the marketing authorisation applied for the fee shall be–

(a) where a major application was previously made in respect of the Article 15.2 marketing authorisation, £7,605; and

(b) where a complex application was previously made in respect of the Article 15.2 marketing authorisation, £5,975.

4. 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 product containing the same active ingredient as the product in respect of which the marketing authorisation or 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 (covering export only), relating to the same product as the marketing authorisation or 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.

5.—(1) Subject to sub-paragraphs (2), (3) and (4) below, where an applicant applies in one or more applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or the same combination of active ingredients, the total of the fees payable by him shall equal the aggregate of the amounts payable under paragraph 1 in respect of separate applications for each product licence or type of authorisation.

(2) Subject to sub-paragraphs (3) and (4) below, where an applicant has made an original request (that is to say a set of one or more applications as described in sub-paragraph (1) above) and either–

(a) withdraws each application in the original request and substitutes for them a new application for one or more products containing the same active ingredients or combination of active ingredients as those in the original request, or

(b) withdraws some but not all of the applications in the original request,

then there shall be calculated in respect of the new or (as the case may be) remnant applications the total of the fees which would have been charged for them had they alone comprised the original request, and that total shall be payable in respect of the new or (as the case may be) remnant applications, but there shall be allowed against it the net total of any fees payable in respect of the original request (that is to say the total so payable less any amount of that total waived, reduced or refunded under these Regulations).

(3) Where an applicant applies in one or more major applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or combination of active ingredients the fee payable for each major application for a marketing authorisation or product licence shall be the amount payable in respect of a major application under paragraph 1 in respect of the first major application and for each major application additional to the first–

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

(b) which relates to a product of the same dosage form but of a different strength of any active ingredient, the amount payable in respect of a standard application under paragraph 1.

(4) Where an applicant applies in one or more complex applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or combination of active ingredients, the fee payable for each complex

application for a marketing authorisation or product licence shall be the amount payable in respect of a complex application under paragraph 1 in respect of the first complex application, and for each complex application additional to the first–

(a) which relates to a product of a different dosage form, the amount payable in respect of a standard application under paragraph 1; and

(b) which relates to a product of the same dosage form but of a different strength of any active ingredient, the amount payable in respect of a simple application under paragraph 1.

(5) This paragraph applies in relation to fees which would, but for this paragraph, be payable by reference to paragraph 1, whether or not as qualified by paragraph 4.

Manufacturer's licences

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

(a) in a case to which sub-paragraph (2) below applies, £95; or

(b) in any other case £2,040; 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 paragraph applies in the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of–

(a) products the sale or supply of which do not require a marketing authorisation or product licence and to which article 2(2)(i) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**1**) applies; or

(b) emergency vaccines.

Wholesale dealer's licences

7.—(1) Subject to the following provision of this paragraph, the fee for an application for a wholesale dealer's licence is £1,185.

(2) Where an applicant for a wholesale dealer's licence anticipates that his turnover in his first calendar year of trading will be less than £40,000, he may pay a provisional fee of £480 if his payment is accompanied by an estimate of such turnover for that year, which shall, subject to the following provisions of this paragraph, be crystallised as his final fee for his application.

(3) Following the first anniversary of the grant of a wholesale dealer's licence, where a wholesale dealer has sent with his application for a wholesale dealer's licence such an estimate of turnover for his first calendar year of trading, he shall, together with his payment of the annual fee payable pursuant to regulation 13(1), send a declaration certifying his turnover for his first calendar year of trading.

(4) If either a declaration, as required by sub-paragraph (3) above, is not sent or the declaration, sent in accordance with sub-paragraph (3) above, shows that the wholesale dealer's turnover for his first calendar year of trading was £40,000 or more, the wholesale dealer shall pay the balance in accordance with regulation 17(3)(b).

(5) Where a wholesale dealer has paid the full fee specified in sub-paragraph (1) above but his turnover for his first calendar year of trading was less than £40,000, if he sends a declaration certifying that turnover, the relevant authority shall refund the excess in accordance with regulation 17(3)(a).

(6) For the purposes of this paragraph, "turnover" has the same meaning as in regulation 13, "trading" means trading as a wholesale dealer, and "balance" and "excess" both mean the difference

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

between the sum payable under sub-paragraph (1) and the sum payable under sub-paragraph (2) above.

Animal test certificates

8. The fee for an application for an animal test certificate in relation to a product which is a biological product or is for administration to non food-producing animals is £250, and for any other application for an animal test certificate is £600.

Marketing authorisation (parallel import)

9. The fee for an application for a marketing authorisation (parallel import) is £1,415.

PART III

FEES RELATING TO APPLICATIONS FOR ASSISTANCE IN CONNECTION WITH MUTUAL RECOGNITION APPLICATIONS

1. Subject to paragraphs 3 and 4, where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to not more than five member States, the fee for such application shall be the fee specified in the corresponding entry in column (2) of that Table.

2. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to more than five member States, the fee for such application shall be the fee specified in the corresponding entry in column (2) of Table C, plus the additional fee specified in the corresponding entry in column (3) of that Table for the sixth and each additional member State.

3. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and an application for such assistance in respect of the same authorisation has previously been made by the applicant, no fee shall be payable in respect of the new application if the total number of member States to which the previous application and the new application relate does not exceed five.

4. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and

(a) an application for such assistance in respect of the same authorisation has previously been made by the applicant; and

(b) the total number of member States to which the previous application related exceeds five,

the fee in column (3) of Table C shall be payable for the sixth and each additional member State exceeding five to which the new application relates.

Table C

Column (1) *Kind of application*	*Column (2)* *Basic fee*	*Column (3)* *Additional Fee for the sixth and each additional member State*
Major	£3,250	£700
Complex	£2,175	£340
Standard	£940	£175
Simple	£315	£60

5.—(1) Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to not more than five member States, the fee for such application shall, subject to sub-paragraph (3) below, be the fee specified in the corresponding entry in column (2) of Table D.

(2) Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to more than five member States, the fee for such application shall, subject to sub-paragraph (3) below, be the fee specified in the corresponding entry in column (2) of Table D plus, for the sixth and each additional member State, the fee specified in the corresponding entry in column (3) of that Table.

(3) Where an application for assistance in connection with a mutual recognition application of a kind described in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and an application for such assistance in respect of the same authorisation has previously been made by the applicant, the fee specified in the corresponding entry in column (3) of Table D shall be payable for each additional member State which was not covered by the previous application.

Table D

Column (1) *Kind of application*	*Column (2)* *Basic fee*	*Column (3)* *Additional fee for the sixth and each additional member State*
Category I application	£7,975	£1,000
Category II application	£5,320	£665
Category III application	£4,255	£530

PART IV

FEES RELATING TO APPLICATIONS FOR THE VARIATION OF MARKETING AUTHORISATIONS, PRODUCT

LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations (other than mutually recognised marketing authorisations) and product licences

1. The fee for a complex application for the variation of–

(a) a marketing authorisation, other than a mutually recognised marketing authorisation, or

(b) a product licence,

is £2,000 in respect of each individual variation.

2. The fee for an application of a kind described in an entry in column (1) of Table E for the variation of–

(a) a marketing authorisation, other than a mutually recognised marketing authorisation; or

(b) a product licence,

other than a complex application, is that specified in the corresponding entry in column (2) of that Table.

Table E

Column (1) *Kind of application*	*Column (2)* *Fee*
Variation requiring veterinary, scientific or pharmaceutical assessment (where the authorisation or licence is not related solely to an emergency vaccine)	£500 for each individual variation in that application plus £200 for each additional consequential individual variation to other authorisations or licences in identical terms
Variation not requiring veterinary, scientific or pharmaceutical assessment (where the authorisation or licence is not related solely to an emergency vaccine)	£200 in respect of each individual variation
Variation where the authorisation or licence relates solely to an emergency vaccine	£40 in respect of each individual variation

Mutually recognised marketing authorisations

3. Subject to paragraph 4, the fee for an application for the variation (of a kind described in an entry in column (1) of Table F) of a mutually recognised marketing authorisation shall, in respect of each individual variation to which the application relates, be that specified in the corresponding entry in column (2) of that Table where the United Kingdom is acting as the Reference Member State and that specified in the corresponding entry in column (3) of the said Table where the United Kingdom is not acting as the Reference Member State–

Table F

Column (1) *Kind of application*	*Column (2)* *Fee–United Kingdom acting as the Reference Member State*	*Column (3)* *Fee–United Kingdom not acting as the Reference Member State*
Type I variation—Administrative	£530	£100
Type I variation—Scientific	£2,130	£500
Type I variation, Scientific—Type II procedure	£3,500	£1,000
Type II variation	£7,445	£2,000
Variation with extras	£8,510	£3,560

4. The fee for an application for a connected variation, that is to say a variation (of a kind described in an entry in column (1) of Table F) of a mutually recognised marketing authorisation which is consequential on, additional and in identical terms to an actual or proposed variation of another such authorisation covered both by the same applicant and by a fee paid in pursuance of paragraph 3 shall, in respect of each connected variation to which the application relates, be £530 per individual variation where the United Kingdom is acting as the Reference Member State and £100 per individual variation where the United Kingdom is not acting as Reference Member State.

Manufacturer's licences

5. The fee for an application for the variation of a manufacturer's licence–

(a) in the case of a manufacturer's licence referred to in paragraph 6(2) of Part II of this Schedule, is £95, and

(b) in any other case–

(i) requiring veterinary, scientific or pharmaceutical assessment, is £360, and

(ii) not requiring veterinary, scientific or pharmaceutical assessment, is £120,

in respect of each individual variation.

Wholesale dealer's licences

6. The fee for an application for the variation of a wholesale dealer's licence–

(a) requiring veterinary, scientific or pharmaceutical assessment, is £360, and

(b) not requiring veterinary, scientific or pharmaceutical assessment, is £120,

in respect of each individual variation.

Animal test certificates

7. The fee for an application for the variation of an animal test certificate is £200 in respect of each individual variation.

PART V

FEES RELATING TO APPLICATIONS FOR THE RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations and product licences

1. Subject to paragraph 4, the fee for an application for the renewal of a marketing authorisation or product licence (or the grant of such an authorisation or licence in circumstances in which regulation 11(2) applies)–

(a) that relates solely to an emergency vaccine is £40,

(b) that relates to a herbal product is £300, and

(c) in any other case is £900.

Manufacturer’s licences

2. The fee for an application for a renewal of a manufacturer’s licence referred to in paragraph 6(2) of Part II of this Schedule is £90.

Animal test certificates

3. The fee for an application for renewal of an animal test certificate is £90.

Article 15.2 marketing authorisations

4. Where an Article 15.2 marketing authorisation is renewed, no fee is payable in respect of the first such renewal.