STATUTORY INSTRUMENTS

1992 No. 694

MEDICINES

The Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1992

Made - - - -	*12th March 1992*
Laid before Parliament	*13th March 1992*
Coming into force - -	*3rd April 1992*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of the powers conferred by section 1(1) and (2) of the Medicines Act 1971(**1**) and now vested in them(**2**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**3**), hereby make the following Regulations:

PART I

GENERAL

Citation, commencement and scope

1.—(1) These Regulations may be cited as the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1992 and shall come into force on 3rd April 1992.

(2) These Regulations apply only to fees payable—

(**1**) 1971 c. 69 as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) as amended by the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388). The expression "the Ministers" is defined in section 1(1) of the 1968 Act as so amended.

(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969; in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragrph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) See section 129(6) of the Medicines Act 1968 as extended to include Regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

(a) in connection with applications for the grant, variation or renewal of licences or certificates under Part II of the Act relating wholly or partly to medicinal products for animal use;

(b) in respect of inspections made in connection with applications for the grant, renewal or variation of, or during the currency of, any such licence or certificate; or

(c) in respect of any reference to the Veterinary Products Committee or to the Medicines Commission in connection with an application for the grant of a product licence under Part II of the Act relating wholly or partly to medicinal products for animal use.

Interpretation

2.—(1) In these Regulations, unless the context requires otherwise—

"the Act" means the Medicines Act 1968(**4**);

"annual fee" in relation to any product licence means the appropriate amount calculated in accordance with the provisions of Part II of Schedule 4;

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

"capital fee" means any fee (other than an annual fee) payable under the provisions of these Regulations;

"emergency vaccines" means vaccines 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 licensed vaccines are readily available for such use;

"licence year" means the period beginning with the first day of April and ending with the last day of March of the year next ensuing;

"medicinal product" includes any substance or article specified in any Order made under (i) section 104 or 105(1)(a) of the Act which directs that Part II of the Act shall have effect in relation to such substance or article; or (ii) section 130(3A) of the Act(**5**) which provides that such substance or article shall be treated as a medicinal product.

(2) In these Regulations, unless the context otherwise requires, any reference to a regulation or a Schedule shall be construed as a reference to a regulation contained in these Regulations, or as the case may be, to a Schedule thereto, and any reference in a regulation or a Schedule to a paragraph shall be construed as a reference to a paragraph of the regulation or, as the case may be, Schedule.

PART II

CAPITAL FEES FOR APPLICATIONS FOR LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

Applications for licences and certificates

3. Subject to regulations 18 and 20, in connection with an application for a product licence, a manufacturer's licence, a wholesale dealer's licence, an animal test certificate, an animal test (confirmation of exemption) certificate or any other certificate of exemption issued under the Act, there shall be payable by the applicant—

(a) the fee prescribed in Part II of Schedule 1 in connection with that application;

(**4**) 1968 c. 67.
(**5**) Section 130 was extended by section 13(2) Animal Health and Welfare Act 1984 (c. 40).

(b) in respect of any inspection specified in Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

Variations of licences and certificates

4. Subject to regulations 5, 6, 18 and 20, in connection with an application under section 30 of the Act for the variation of a provision of a product licence, a manufacturer's licence or a wholesale dealer's licence, under section 39(4) in respect of an animal test certificate or an animal test (confirmation of exemption) certificate, there shall be payable by the applicant—

(a) the fee prescribed in Part III of Schedule 1; and

(b) in respect of any inspection specified in Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Applications for multiple variations

5. A separate fee shall be payable in respect of each variation of each provision of a licence or certificate applied for in any one application except that no separate fee shall be payable in respect of any variation which is related to or is consequential upon another variation of a provision of the same licence or certificate which is applied for in the same application.

Variations at the invitation of the licensing authority

6. Where an application for a variation is made at the express written invitation of the licensing authority, no fee shall be payable under this Part of these Regulations.

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES OR CERTIFICATES AND FOR INSPECTIONS IN CONNECTION THEREWITH

Renewal of licences and certificates

7. Subject to regulations 8, 18 and 20, in connection with an application under section 24(2) of the Act for renewal of a product licence, a manufacturer's licence or a wholesale dealer's licence, and under section 38(2) for an animal test certificate or an animal test (confirmation of exemption) certificate, there shall be payable by the applicant—

(a) the appropriate fee prescribed in Part IV of Schedule 1; and

(b) in respect of any inspection specified in Schedule 2 made in connection with that application, the fee payable in accordance with paragraphs 2 to 6 of that Schedule.

Renewals in terms which are not identical to the existing licence or certificate

8. Where an applicant applies for renewal of a licence, or as the case may be, an animal test certificate so as to contain provisions which are not identical to that licence or certificate as in force at the date of that application, the fee payble under this Part of these Regulations shall be increased

by an amount equal to the fee which would have been payable under Part III of these Regulations had he made a separate application for each variation of that licence or certificate.

PART V

FEES FOR INSPECTIONS OF A SITE MADE DURING THE CURRENCY OF A LICENCE

Inspections of a site

9.—(1) Subject to paragraph (4) and to regulations 18 and 20, a fee in accordance with paragraphs 2 to 6 of Schedule 2 shall be payable in respect of any inspection of a site made during the currency of a product licence, a manufacturer's licence or a wholesale dealer's licence (except for any inspection in respect of which a fee is otherwise payable under Parts III or IV of these Regulations).

(2) The fee payable under paragraph (1) in respect of an inspection of a site made during the currency of a manufacturer's licence or a wholesale dealer's licence shall be payable by the holder of the manufacturer's licence or, as the case may be, the wholesale dealer's licence.

(3) Where a fee is payable under paragraph (1) in respect of an inspection of a site located outside the United Kingdom, the fee shall be payable in equal proportions by each holder of a product licence in which that site is named as a possible site for manufacture of the medicinal product in respect of which the product licence is granted.

(4) No fee shall be payable in respect of any inspection of a site carried out within 6 months of a previous inspection in order to ascertain whether alterations or improvements to the premises concerned, which were required in writing by the licensing authority as the result of that previous inspection, have been implemented.

PART VI

ANNUAL FEES

Product licences — annual fee

10.—(1) Subject to paragraph (3) and regulation 20, in connection with any application for the grant or renewal of any product licence, there shall be payable by the applicant an annual fee in respect of each calendar year—

(a) throughout which the product licence (having been granted or renewed) is in force; or

(b) during any part of which the product licence (already held by the applicant) is or was in force

and (in either case) the applicant has sold, supplied or manufactured any medicinal product to which the licence relates.

(2) The annual fee shall be calculated in accordance with Schedule 4.

(3) The annual fee may be adjusted or refunded in any of the circumstances set out in Schedule 5.

PART VII

REFERENCES TO VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION

Product licences and animal test certificates — references

11. Subject to regulation 18, in respect of any reference to the Veterinary Products Committee or to the Medicines Commission under section 21 of the Act in connection with a product licence or an animal test certificate, there shall be payable by the applicant at the time of the application the appropriate fee prescribed in Schedule 6.

PART VIII

ADMINISTRATION

Payment of fees to Ministers

12. Any sums which under the provisions of these Regulations become payable by way of, or on account of, fees shall be paid to one of the Agriculture Ministers specified in section 1(1)(b) of the Act as appropriate.

Time for payment of capital fees in connection with applications or inspections and refunds of such fees

13.—(1) Subject to paragraphs (2) and (3), all sums payable by way of capital fees under these Regulations in connection with any application shall be payable at the time of the application.

(2) If, following either the determination of an application or an inspection, it becomes apparent that—

(a) a lesser fee was properly payable, the excess shall be refunded to the applicant, or as the case may be, the holder of the licence or certificate concerned within 28 days of a request for a refund; or

(b) a higher fee was properly payable, the balance due shall be payable within 28 days following written notice from the licensing authority to the applicant or, as the case may be, the holder of the licence or certificate concerned.

(3) All sums payable by way of fees in respect of inspections made either in connection with an application or during the currency of a licence or certificate or in respect of samples submitted for testing shall become payble within 28 days following written notice from the licensing authority.

Time for payment of annual fees

14. All annual fees shall be payable during September of the licence year following the calendar year to which they relate.

Late payment of annual fees

15.—(1) Where an annual fee has not been paid by the holder or former holder of the licence by the end of the period of three months from the due date, a further fee, calculated in accordance with the provisions of the following paragraphs, shall be payable.

(2) The further fee referred to in the preceding paragraph shall be an amount equivalent to 5 per cent of the annual fee payable, in respect of every full calendar month during which the annual fee

is not paid, rounded up to the nearest £10. Where the annual fee payable is less than £10, no such further fee shall be payable.

(3) Where the holder or former holder of a licence has not furnished evidence of his annual turnover in accordance with the provisions of Part I of Schedule 4 so that the annual fee payable in respect of a licence year cannot be determined before the due date, he may make a payment of an amount on account of the annual fee payable by him (in this regulation referred to as a "payment on account").

(4) Where the holder or former holder of a licence has made a payment on account in the circumstances mentioned in the preceding paragraph the further fee payable by him shall be calculated as if, in paragraph (2) above, the reference to the annual fee payable were to the difference between the payment on account and the amount of the annual fee as subsequently determined.

(5) In this regulation—

(a) "due date" means the date upon which an annual fee becomes payable following written notice from the licensing authority;

(b) references to a period calculated from a day are references to the period inclusive of that day.

Suspension of licences

16. Where any sum due by way of, or on account of, any fee or any part thereof payable under these Regulations remains unpaid by the holder of a licence or certificate, the licensing authority may serve a notice on him requiring payment of the sum unpaid and, if after a period of one month from the date of service of such notice, or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence or certificate until such sum has been paid.

Civil proceedings to recover unpaid fees

17. All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.

Waiver, reduction or refund of fees

18. The licensing authority may waive payment of, reduce any fee or part of a fee otherwise payable under these Regulations or refund the whole or part of any fee already so paid in exceptional circumstances or in any of the circumstances specified in Schedule 3.

PART IX

REVOCATION, SAVINGS AND TRANSITIONAL PROVISIONS

Revocation and savings

19.—(1) Subject to paragraph (2), the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1991(**6**) are hereby revoked.

(2) Paragraph (1) shall not affect—

(a) any annual fee or part of such a fee under the Regulations hereby revoked;

(**6**) S.I. 1991/632, amended by S.I. 1991/2063.

(b) any notice given or any suspension made under the Regulations hereby revoked and any such notice or suspension shall have effect as if given or made under these Regulations; and

(c) any proceedings instituted under the Regulations hereby revoked for the recovery of any fees due as debts due to the Crown.

Transitional provisions

20.—(1) Subject to paragraphs (2) and (3), these Regulations shall not apply to any application made before the date these Regulations come into force.

(2) A fee shall be payable in respect of any inspection made or any product testing required after the date these Regulations come into force in connection with any application made before that date as if these Regulations applied to that application.

(3) Where an application is made before the date these Regulations come into force to renew a licence or certificate which is due to expire on or after 1st July 1992 a fee shall be payable in accordance with Part IV of these Regulations in connection with that application within 28 days following written notice from the licensing authority.

Virginia Bottomley
10th March 1992 Minister of State for Health

David Hunt
10th March 1992 Secretary of State for Wales

Strathclyde
Parliamentary Under Secretary of State, Scottish
10th March 1992 Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th March 1992.

hereunto affixed

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 11th March 1992.

hereunto affixed

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 12th March 1992.

hereunto affixed

L.S.

W. J. Hodges
Permanent Secretary

We consent,

Gregory Knight
Thomas Sackville
Two of the Lords Commisssioners of Her Majesty's Treasury

10th March 1992

SCHEDULE 1 Regulations 3(a) 4(a) and 7(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 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(**7**)(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

(**7**) OJ No. 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) in 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(**8**) 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. £13,250
2. Complex application	2. £ 7,700
3. Standard application	3. £ 3,300
4. Simple application	4. £ 1,100
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

(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,

(**8**) OJ No. L270, 23.11.70, p. 1, as amended by Council Directive 84/587/EEC, OJ No. L319, 8.12.84, p. 13.

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) 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 payable under regulation 3(a) shall be 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 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.

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 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(**9**) applies; or

(b) emergency vaccines.

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

Wholesale dealers' licences

6.—(1) Subject to paragraph (2) below the fee payable under regulation 3(a) in connection with an application for a wholesale dealer's licence shall be £1,260.

(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 an auditor's certificate certifying the low turnover, shall be £425.

(3) For the purposes of this paragraph, "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 calendar year which ends three months before the beginning of the licence 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.

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(**10**) shall be—

(a)	in respect of new molecules—	
	(i) in food producing animals	£2,625
	(ii) in non-food producing animals	£1,310
(b)	in respect of non-licensed inactivated vaccines	£2,625
(c)	in respect of licensed live vaccines	£1,575
(d)	in respect of licenced inactivated vaccines	£1,575
(e)	any other application	£ 525

PART III

FEES FOR APPLICATIONS FOR VARIATIONS OF LICENCES OR CERTIFICATES

Product licences

1. The fee payable under regulation 4(a) in connection with an application for variation of a product licence—

(a) in the case of a complex application, shall be £1,100;

(b) in any other case—

(**10**) S.I. 1986/1180, amended by S.I. 1991/633.

(i) requiring veterinary, scientific or pharmaceutical assessment—

(aa) for a variation, shall be £320;

(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;

(iii) where the variation applied for involves the reissue of the product licence in the new name of the company, shall be £110;

(iv) where the product licence relates solely to an emergency vaccine, shall be £30.

Manufacturers' licences

2. The fee payable under regulation 4(a) in connection with 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 £320;

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

Wholesale dealers' licences

3. The fee payable under regulation 4(a) in connection with an application for variation of a wholesale dealer's licence—

(a) requiring veterinary, scientific or pharmaceutical assessment, shall be £320;

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

Animal test certificates

4. The fee payable under regulation 4(a) in connection with an application for variation of an animal test certificate—

(a) in the case of a complex application, shall be £1,100;

(b) in any other case—

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £320;

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

(iii) where the variation applied for involves the reissue of the animal test certificate in the new name of the company, shall be £110; or

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

(i) requiring veterinary, scientific or pharmaceutical assessment, shall be £320;

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

(iii) where the variation applied for involves the reissue of the animal test (confirmation of exemption) certificate in the new name of the company, shall be £110.

PART IV

FEES FOR APPLICATIONS FOR RENEWALS OF LICENCES

Product licences

1. The fee payable under regulation 7(a) in connection with an application for renewal of a product licence shall be £440, and, in the case of a licence relating solely to an emergency vaccine, £30.

Manufacturers' licences

2. The fee payable under regulation 7(a) in connection with an application for renewal of a manufacturer's licence—

(a) referred to in paragraph 5(2) of Part II of this Schedule, shall be £90;

(b) in any other case, shall be an annual fee of £195 payable on the annual renewal date of the licence.

Wholesale dealers' licences

3.—(1) Subject to paragraph (2) below, the fee payable under regulation 7(a) in connection with an application for renewal of a wholesale dealer's licence shall be an annual fee of £125 payable on the annual renewal date of the licence.

(2) In the case of a wholesale dealer who has a turnover in 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 renewal of a wholesale dealer's licence, accompanied (in either case) by an auditor's certificate certifying the low turnover, shall be £80.

(3) For the purposes of this paragraph, "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 calendar year which ends three months before the beginning of the licence 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.

Animal test certificates

4. The fee payable under regulation 7(a) in connection with an application for renewal of—

(a) an animal test certificate, shall be £525;

(b) an animal test (confirmation of exemption) certificate, shall be £315.

SCHEDULE 2

Regulations 3(b), 4(b), 7(b) and 9

FEES FOR INSPECTIONS

Interpretation

1.—(1) In this Schedule—

"dormant biological medicinal product" means a product which is not currently being manufactured or sold and in respect of which there is no current intention to recommence the manufacture or sale;

"major inspection" means an inspection at a site at which 60 or more, but fewer than 250, relevant persons are employed;

"minor inspection" means an inspection at a site at which fewer than 10 relevant persons are employed;

"relevant person" means any person directly or indirectly engaged in, or assisting in, the manufacture or assembly of medicinal products and also includes any person connected with such production who is involved in management, quality control, site maintenance, packing, storage or distribution;

"standard inspection" means an inspection at a site at which 10 or more, but fewer than 60, relevant persons are employed;

"supersite inspection" means an inspection at a site at which 250 or more relevant persons are employed.

(2) In calculating the number of relevant persons for the purposes of this Schedule, any person partly engaged or assisting in the manufacture or assembly of medicinal products (whether as a part-time employee or by virtue of being only partly employed in such work) shall be included in the calculation but only as a fraction calculated by reference to the amount of time spent by that person engaged or assisting in the manufacture or assembly of medicinal products or, where such a calculation is inappropriate, by reference to the percentage of his job which relates to the manufacture or assembly of such products and, in either case, by comparison with the average working week of a relevant person engaged in full-time employment at the same site.

Fees

2. Subject to paragraphs 3 to 5, the fee payable in respect of an inspection under these Regulations shall be—

(a) except in the case of an inspection falling within sub-paragraphs (b) to (d) below—

(i) in respect of a minor inspection, £1,450;

(ii) in respect of a standard inspection, £2,900;

(iii) in respect of a major inspection, £5,800;

(iv) in respect of a supersite inspection, £10,915;

(b) where the site inspected is wholly or partly concerned with the manufacture of sterile products or the filling of the containers directly in contact with such products—

(i) in respect of a minor inspection, £2,415;

(ii) in respect of a standard inspection, £4,825;

(iii) in respect of a major inspection, £9,600;

(iv) in respect of a supersite inspection, £18,190;

(c) except in the case of an inspection falling within sub-paragraph (b) above or sub-paragraph (d) below, where the site inspected is concerned only with the assembly of medicinal products—

(i) in respect of a minor inspection, £975;

(ii) in respect of a standard inspection, £1,925;

(iii) in respect of a major inspection, £3,850;

(iv) in respect of a supersite inspection, £5,670;

(d) where the site inspected is limited solely to the manufacture or assembly of—

(i) 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 applies, £90;

(ii) emergency vaccines, £90.

3.—(1) Subject to paragraph (2), unless the applicant or, as the case may be, the holder of the licence establishes that an inspection is a minor inspection or a standard inspection, the fee payable shall be the appropriate fee specified in paragraph 2 above for a major inspection.

(2) If, following an inspection, it becomes apparent that the inspection fell into a different category from that established by the applicant or the holder of the licence, the fee payable under these Regulations in respect of that inspection shall be the fee payable in respect of an inspection falling within the category into which the inspection should have fallen.

4.—(1) In the case of an inspection in connection with the grant, variation or renewal of a wholesale dealer's licence or during the currency of such a licence, the fee payable under these Regulations—

(a) except in a case falling within sub-paragraph (b) or (c) shall be, £1,260;

(b) where the site is that of a wholesale dealer whose licence is limited to dealing only in medicinal products falling within a description or class of such products specified in an Order made under section 51(1) of the Act, shall be £480;

(c) where the site is that of a wholesale dealer who has a turnover in respect of veterinary medicinal products—

(i) of less than £30,000; or

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

and if he produces (in either case), on request, an auditor's certificate certifying the low turnover, shall be £480.

(2) For the purposes of this paragraph, "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 calendar year which ends three months before the beginning of the licence 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.

5. The fee payable in respect of any inspection of the premises and the procedures used or any inspection of the premises or the procedures used for the quality control of a biological medicinal product in respect of which a product licence has been granted or applied for, shall be £1,050 for each such product which is not a dormant biological medicinal product. Any such inspection in connection with such a licensed biological medicinal product (not being a dormant biological medicinal product) in respect of which a product licence was granted because it was identical to an existing product, shall be £55.

6. The fee payable in respect of an inspection at a site outside the United Kingdom shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs reasonably incurred by him in respect of that inspection as a result of its being at a site outside the United Kingdom (such as interpreter's fees). The fee payable in respect of an inspection pursuant to paragraph 5 above at a site, whether or not outside the United Kingdom, shall be increased by an amount equal to the travelling and subsistence costs of the inspector relating to the inspection and any additional costs reasonably incurred by him in respect of that inspection in the case of its being at a site outside the United Kingdom (such as interpreter's fees).

SCHEDULE 3

Regulation 18

WAIVER, REDUCTION OR REFUND OF CAPITAL FUNDS

1. Where the manufacture, assembly, sale or supply of medicinal products of a particular class or description will be, or is likely to be, interrupted for a period, and in consequence thereof the health of animals will be, or is likely to be, put at risk, the licensing authority may decide that any fees otherwise payable under these Regulations—

(a) in connection with an application for the grant (variation or renewal) of a product licence relating to a medicinal product falling within that class or description; or

(b) in respect of any inspection made during the currency of such a licence

shall be waived during that particular period or, if the period will, or is likely to, exceed 3 months, during the first 3 months of that period.

2. The licensing authority may waive or reduce the payment of any capital fee payable under these Regulations in circumstances where—

(a) in its opinion the interests of human or animal health require a licence or certificate to be granted or an inspection to be made; and

(b) the medicinal product in respect of which an application for a licence or certificate has been made—

(i) is not intended for sale; or

(ii) is intended only for use in the treatment of rare conditions or in the treatment of a minor species of animal or as an emergency vaccine.

3.—(1) Subject to sub-paragraphs (2) to (5) below, where the licensing authority—

(a) is satisfied that the annual turnover (as calculated in accordance with Part I of Schedule 4) of a medicinal product during any calendar year of the first five years of the currency of the product licence, has not exceeded, or is unlikely to exceed, £30,000; and

(b) is of the opinion that the interests of human or animal health require a product licence to be granted

any capital fee otherwise payable under these Regulations in connection with an application for a product licence or an inspection during the currency of that licence, may be reduced or, if such a fee has already been paid, be refunded in part in proportion to the difference between the maximum turnover of the product in any calendar year (during any of the first five years of the currency of the licence) and the sum of £30,000.

(2) Before a licence holder pays any reduced fee or receives any refund pursuant to sub-paragraph (1), he shall furnish evidence to the satisfaction of the licensing authority of the amount of annual turnover, in respect of the particular medicinal product, in each calendar year of the first five years of the currency of the licence.

(3) Where a reduced fee is determined in accordance with sub-paragraph (1) above at the time of application on the basis of the estimated likely maximum turnover of the medicinal product during the first five years of the currency of the licence, any fee so determined shall be regarded as a provisional payment on account.

(4) Where a provisional payment on account is made in accordance with sub-paragraph (3) above and subsequently the turnover in any calendar year in the first five years of the currency of the licence exceeds £30,000, the licence holder shall be liable to pay the balance of the full fee otherwise payable under these Regulations within 28 days of notification by the licensing authority.

(5) Where any provisional payment on account is made in accordance with sub-paragraph (3) above, the reduced fee shall be recalculated in accordance with the provisions of sub-paragraph (1)

above at the end of five years from the date of the grant of the licence and any difference between the fee so calculated and the provisional payment on account shall be payable by the applicant or, as the case may be, refunded to the applicant by the licensing authority within 28 days of a request for such a refund.

4. Where an application for the grant or renewal of a product licence is made at the specific written request of the licensing authority any fee otherwise payable under these Regulations in connection with that application shall be waived.

5.—(1) Subject to sub-paragraph (2) below, where an application for a product licence is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable (under regulation 3(a)) in connection with that application shall be refunded or, if it has not yet been paid, shall be waived—

(a) if the application has been received but no veterinary scientific or pharmaceutical assessment thereof has begun, 90%;

(b) except in a case to which sub-paragraph (c) below applies, veterinary, scientific or pharmaceutical assessment has begun but not been completed, 50%;

(c) if a request for further information in connection with the application has been made by the licensing authority under section 44(1) of the Act, 25%.

In the case of sub-paragraph (b) above, where an application has been withdrawn because it is deficient and a 50% refund of the fee has been made by the licensing authority, any subsequent reapplication in respect of the same product licence by the same applicant shall be charged at 50% of the fee otherwise payable under regulation 3(a).

(2) If an application for a product licence is withdrawn either after scientific or veterinary pharmaceutical assessment has been completed or following consideration of that application by a committee established under section 4 of the Act or by the Medicines Commission, no refund or waiver of the fee payable (under regulation 3(a) of these Regulations) in connection with that application shall be made under this paragraph.

(3) Where the same site is inspected at the same time in connection with applications for the grant, variation, or renewal of both a manufacturer's licence and a wholesale dealer's licence or during the currency of both such licences, the fee otherwise payable under these Regulations in respect of the inspection relating to the wholesale dealer's licence shall be waived.

SCHEDULE 4

Regulation 10(2)

ANNUAL FEES FOR PRODUCT LICENCES

PART I

CALCULATION OF TURNOVER

1. In relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule, "manufacturers' prices" shall mean, subject to the provisions of paragraph 2, the prices charged by manufacturers to wholesalers, except where medicinal products are supplied by manufacturers direct to retailers, in which case the prices charged by the licence holder may be reduced by such sum as, in the opinion of the licensing authority represents the difference between the prices paid by wholesalers and those normally charged by them to retailers according to the practice prevailing during the licence year in question with regard to such products.

2. Where a licence holder sells or supplies medicinal products which he has neither manufactured nor obtained from the manufacturer, in relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule "manufacturers' prices" shall mean the prices paid by, or on behalf of, the licence holder for those medicinal products.

3.—(1) For the purpose of calculating annual fees for product licences for intermediate feed in relation to the calculation of turnover in any calendar year in accordance with the provisions of the succeeding paragraphs of this Part of this Schedule, the value of the feedingstuff shall be included in the value of the intermediate feed.

(2) For the purposes of this Part of this Schedule, "intermediate feed" means a medicated feedstuff sold, supplied or imported for use wholly or mainly as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose, with or without further processing.

4. For the purpose of calculating annual fees for product licences of a particular kind, "turnover" means the gross value at manufacturer's prices of all medicinal products sold or supplied by the applicant in the United Kingdom during the calendar year which ends 3 months before the beginning of the licence year. For the purposes of this paragraph medicinal products sold or supplied by the licence holder shall comprise only those products in respect of which a licence is held during that calendar year.

5. Where the licence holder fails to furnish evidence of the amount of annual turnover to the satisfaction of the licensing authority the licensing authority may require the licence holder to furnish an auditor's certificate containing such evidence. If within one month of the date by which such certificate is required to be furnished, or such longer period as the licensing authority may allow, the licence holder has failed to furnish such certificate the sum payable by way of fees for the licence year in question shall be calculated as provided for in paragraph 4 of Part II of this Schedule or shall be such lesser sum as the licensing authority shall specify in a notice served on the licence holder.

6. Where an applicant for a licence was not dealing in medicinal products during the calendar year which ends 3 months before the beginning of the licence year in which the application is made, but has taken over an existing business or concern, whether by purchase or merger or otherwise, the gross value of sales of that business or concern during the calendar year which ends 3 months before the beginning of the licence year in which the application is made may be treated as the gross value of sales for the purpose of calculating the turnover of that business or concern.

PART II

CALCULATION OF ANNUAL FEES

1. Subject to the provisions of these Regulations annual fees shall be payable at the basic rate of £250 or 0.63% of turnover, whichever is the greater.

2. For the purpose of calculating annual turnover the provisions of Part I of this Schedule shall apply.

3. The amount payable by way of annual fees in accordance with this Schedule shall, when calculated on the basis of turnover, be rounded up to the nearest £10.

4. Where in any licence year the licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the licencing authority the annual fee payable by him in respect of that licence year shall be the sum of £10,000 together with an additional £2,000 for each description of medicinal product in respect of which a licence is held by the licence holder.

5. Where the holder of, or an applicant for a product licence is liable to pay an annual fee and his turnover for the purposes of calculating such a fee exceeds £31.5 million, one half of such turnover which is the excess of the said amount of £31.5 million shall be deducted from such turnover for the purpose of calculating the said annual fee.

PART III

CALCULATION OF ANNUAL FEE — EMERGENCY VACCINES

Where the holder of a product licence sells or supplies emergency vaccines, the annual fee payable shall be 0.63% of turnover, calculated in accordance with the provisions of Part I of this Schedule rounded up to the nearest £1, except that the minimum sum payable under this provision shall be £10.

SCHEDULE 5

Regulation 10(3)

ADJUSTMENT OR REFUND OF ANNUAL FEES

1. Where an annual fee has been paid in accordance with these Regulations and the licensing authority is subsequently satisfied as to the gross value of sales, the difference between the amount so paid and the annual fee so calculated may be refunded by the licensing authority.

2. Any sums payable to an applicant by way of refund of any fees under the provisions of this Schedule may be treated as having been paid on account of any other fee which the applicant is liable to pay (whether by instalments or otherwise) under the provisions of these Regulations.

SCHEDULE 6

Regulation 11

FEES FOR REFERENCES TO THE VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION

The fee payable under regulation 12 for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with—

(1) a product licence of the kind described in column 1 of the following Table shall be the fee specified in the corresponding entry in column 2 to of that Table:

Column 1 *Kind of application*	*Column 2* *Appropriate fee*
1. Major application	£1,260
2. Complex application	£ 735
3. Standard application	£ 315
4. Simple application	£ 105

(2) An animal test certificate, shall be £420.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which replace the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1991, as amended, prescribe fees in connection with applications and inspections relating to licences and certificates granted under the Medicines Act 1968 insofar as they apply to medicinal products for animal use. Most fees are increased by approximately 5%.

The Regulations provide for increased fees to be payable for applications for the grant of product licences, manufacturers' licences, wholesale dealers' licences, animal test certificates and exemption certificates (Part II). Fees will no longer be charged for export certificates and the fees for licences relating to emergency vaccines have not been increased. Provision is made for a lower fee to be payable on application for a licence, renewal of a licence or for an inspection of a site by wholesale dealers who have a low turnover in veterinary medicinal products (Schedule 1, Part II, paragraph 6(2), Schedule 1 Part IV, paragraph 3(2), Schedule 2 paragraph 4(1)(c).

The Regulations also provide for increased fees to be payable for applications for variations of such licences or certificates (Part III) and for renewal thereof (Part IV). A fee is introduced for the variation of a complex application for an animal test certificate (Schedule 1, Part III, paragraph 4). The Regulations provide for increased fees to be payable in respect of inspections of sites carried out in connection with applications for licences or certificates. A fee is introduced in respect of supersite (as defined) inspections (Schedule 2, paragraph 2).

The Regulations provide for increased annual fees for product licences to be payable, calculated on the basis of annual turnover but only where the applicant has sold, supplied or manufactured during the licence year, any medicinal product to which the licence relates (regulation 10(1)).

The fee in respect of any appeal in connection with the grant of a product licence to the Veterinary Products Committee or to the Medicines Commission has been increased (regulation 11).

Administrative provisions (Part VIII) deal with time of payment and waiver or refund of fees in specified circumstances.

Part IX of the Regulations deals with revocations, savings and transitional provisions.