STATUTORY INSTRUMENTS

1994 No. 1554

MEDICINES

The Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1994

Made - - - -	*12th June 1994*
Laid before Parliament	*13th June 1994*
Coming into force - -	*4th July 1994*

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:

Citation, commencement and scope

1.—(1) These Regulations may be cited as the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1994 and shall come into force on 4th July 1994.

(2) These Regulations apply only to fees relating wholly or partly to medicinal products for animal use.

Interpretation

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

(**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 paragraph 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.

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

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

"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;

"medicinal product" includes any substance or article specified in any Order made under

(a) 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

(b) section 130(3A) of the Act(**5**) which provides that such substance or article shall be treated as a medicinal product,

and includes any substance or article to be administered in a medicinal test on animals under section 32(6)(c) of the Act.

(2) In these Regulations, unless the context otherwise requires, any reference to a regulation or a Schedule is a reference to a regulation of or Schedule to these Regulations, and any reference in a regulation or a Schedule or Part of a Schedule to a paragraph is a reference to a paragraph of the regulation or Schedule or Part of a Schedule.

Applications for licences and certificates

3. Subject to the following provisions of these Regulations, an applicant for the grant, renewal or variation of a product licence, a manufacturer's licence, a wholesale dealer's licence, or an animal test certificate, shall pay—

(a) the relevant fee prescribed in Schedule 1;

(b) in respect of any inspection in connection with a licence specified in Schedule 2, the relevant fee prescribed in that Schedule and made in accordance with that application.

Applications for multiple variations

4. 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 in the same application.

Variations at the invitation of the licensing authority

5. No fee shall be payable for a variation made at the express written invitation of the licensing authority.

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

6. Where an applicant applies for renewal of a licence or 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 payable shall be the renewal fee plus the fee which would have been payable had a separate application been made for each variation.

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

Inspections of a site

7.—(1) Subject to paragraph (3), the holder of a manufacturer's licence shall pay the relevant fee prescribed in Schedule 2 in respect of any inspection of a site and relating to that licence (except for any inspection for which a fee is payable relating to the grant, variation or renewal of a licence).

(2) Where a product licence specifies a manufacturing site outside the European Union, and the site is inspected, the fee specified in Schedule 2 shall be payable by the product licence holder; and if there is more than one product licence holder, a fee shall be payable by each product licence holder, which shall be the amount specified in Schedule 2 divided between the holders of the product licences in proportion to the number of licences held.

(3) 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.

Product licences: annual fee

8.—(1) The holder of any product licence shall pay an annual fee calculated in accordance with Schedules 3 and 4 in respect of each calendar year in which he has sold, supplied or manufactured any medicinal product to which the licence relates.

(2) All annual fees shall be payable during October of the year following the calendar year to which they relate.

Manufacturers' licences: annual fees

9. The holder of a manufacturer's licence, other than one specified in paragraph 5(2) of Part II of Schedule 1, shall pay an annual fee of £200 payable on each anniversary of the grant of the licence.

Wholesale dealers' licences: annual fees

10.—(1) The holder of a wholesale dealer's licence, other than one specified in paragraph (2), shall pay an annual fee of £400 payable on each anniversary of the grant 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 annual fee for a wholesale dealer's licence, accompanied (in either case) by a declaration certifying the low turnover, shall be £200.

(3) For the purposes of this regulation, "turnover" means the gross value of all licensed veterinary medicinal products sold by way of wholesale dealing by the applicant in the United Kingdom during the previous calendar year.

Product licences and animal test certificates: references

11. 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 5.

Payment of fees to the Minister

12. Fees under these Regulations shall be payable to the Minister of Agriculture, Fisheries and Food.

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

13.—(1) All fees under these Regulations in connection with any application (other than fees for inspections) shall be payable at the time of that 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 fees for 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 payable within 28 days following written notice from the licensing authority.

Late payment of annual fees

14.—(1) Where the annual fee for a product licence has not been paid 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.

(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 3 so that the annual fee payable 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 became 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

15. 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.

Waiver, reduction or refund of fees

16. The licensing authority may waive payment of any fee, 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 6.

Revocation and savings

17.—(1) Subject to paragraph (2), the Medicines (Fees Relating to Medicinal Products for Animal Use) Regulations 1992(**6**) are hereby revoked.

(2) Paragraph (1) shall not affect—

(a) any annual fee or part of such a fee under those Regulations;

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

(c) any proceedings instituted under those Regulations.

Transitional provisions

18.—(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 to renew a licence or certificate is made before the date these Regulations come into force, and the licence or certificate is due to expire on or after 1st July 1994 the fee shall be that payable under these Regulations, and the balance due shall be payable within 28 days following written notice from the licensing authority.

Signed by authority of the Secretary of State for Health:

Tom Sackville
Parliamentary Under Secretary of State,
Department of Health

7th June 1994

Signed by the authority of the Secretary of State for Wales:

Wyn Roberts
Minister of State, Welsh Office

12th June 1994

(**6**) S.I. 1992/694.

Hector Monro
Parliamentary Under Secretary of State, Scottish Office

9th June 1994

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

7th June 1994.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland

L.S.

F. A. Elliott
Permanent Secretary

9th June 1994.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland

L.S.

J. Murray
Permanent Secretary

7th June 1994.

We Consent

Timothy Wood
Andrew MacKay
Two of the Lords Commissioners of Her Majesty's Treasury

8th June 1994

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(**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, 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(**8**) 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.

(**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.

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(**9**) 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.

(**9**) 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.

SCHEDULE 2

Regulations 3 and 7

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.—(1) Subject to paragraphs 3 to 5, except in the case of an inspection falling within sub-paragraphs (2) to (4) below the fee payable in respect of an inspection under these Regulations shall be in accordance with the following Table:

Kind of inspection	Fee payable
Supersite inspection	£11,000
Major inspection	£5,800
Standard inspection	£3,100
Minor inspection	£1,650

(2) 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 the fee payable shall be in accordance with the following Table:

Kind of inspection	Fee payable
Supersite inspection	£18,190
Major inspection	£9,600
Standard inspection	£4,850
Minor inspection	£2,500

(3) Except in the case of an inspection falling within sub-paragraph (2) above or sub-paragraph (4) below, where the site inspected is concerned only with the assembly of medicinal products the fee payable shall be in accordance with the following Table:

Kind of inspection	Fee payable
Supersite inspection	£5,900

Kind of inspection	Fee payable
Major inspection	£4,000
Standard inspection	£1,950
Minor inspection	£1,000

(4) Where the site inspected 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 applies, the fee payable shall be £100;

(b) emergency vaccines, the fee payable shall be £100.

3. 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. 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 bioligical medicinal product in respect of which a product licence has been granted or applied for, shall £1,100 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.

5. 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 4 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

Regulations 8 and 14

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 period 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 feedingstuff 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, "turnover" means the gross value at manufacturers' prices of all veterinary medicinal products sold or supplied in the United Kingdom during the previous calendar year and in relation to which the person from whom the fee is due holds the licence.

5. Where the licence holder fails to furnish evidence of the amont 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 period 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 previous calendar year, 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 previous calendar year 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. In the case of a company with a turnover of £2,800,000 or over, the fee payable shall be £150 for each licence held, plus £16,800, plus 0.40% of annual turnover in excess of £2,800,000.

2. In the case of a company with a turnover of less than £2,800,000, the fee payable shall be £250 or 0.60% of annual turnover, whichever is the greater except that a company with no turnover shall be exempt from any annual fee.

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

4. 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.

5. If a licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the licensing authority the annual fee payable by him for that 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.

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 0.60% 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 4

Regulation 8

ADJUSTMENT OR REFUND OF ANNUAL FEES

1. Where an annual fee has been paid in accordance with regulation 8 of 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 5

Regulation 11

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

1. The fee payable under regulation 11 for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with a product licence shall be in accordance with the following Table:

Kind of application	Fee
Major application	£1,300
Complex application	£750
Standard application	£350
Simple application	£125

2. The fee payable under regulation 11 for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with an animal test certificate shall be £450.

SCHEDULE 6

Regulation 16

WAIVER, REDUCTION OR REFUND OF FEES

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 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 3) 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 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) above 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.—(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.

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 1992, 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. Fees are increased on average by approximately 4%.

A Compliance Cost Assessment has been prepared and placed in the library of each House of Parliament.