STATUTORY INSTRUMENTS

1992 No. 694

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

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—

(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(**1**);

"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

(**1**) 1968 c. 67.

relation to such substance or article; or (ii) section 130(3A) of the Act(**2**) 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;

(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.

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

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(**3**) are hereby revoked.

(2) Paragraph (1) shall not affect—

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

(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 Office
10th March 1992

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

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