STATUTORY INSTRUMENTS

1994 No. 1554

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

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—

"the Act" means the Medicines Act 1968(**1**);

"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(**2**) 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.

(**1**) 1968 c. 67.
(**2**) Section 130 was extended by section 13(2) Animal Health and Welfare Act 1984 (c. 40).

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.

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(**3**) 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.

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

Signed by authority of the Secretary of State for Health:

Tom Sackville
Parliamentary Under Secretary of State,
7th June 1994 Department of Health

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

Wyn Roberts
12th June 1994 Minister of State, Welsh Office

Hector Monro
Parliamentary Under Secretary of State, Scottish
9th June 1994 Office

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

L.S.

Gillian Shephard
7th June 1994. Minister of Agriculture, Fisheries and Food

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

L.S.

F. A. Elliott
9th June 1994. Permanent Secretary

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

L.S.

J. Murray
7th June 1994. Permanent Secretary

We Consent

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

8th June 1994