STATUTORY INSTRUMENTS

1998 No. 2428

The Medicines (Products for Animal Use—Fees) Regulations 1998

Citation, commencement and scope

1.—(1) These Regulations may be cited as the Medicines (Products for Animal Use—Fees) Regulations 1998 and shall come into force on 1st November 1998.

(2) These Regulations apply only to fees relating to products for animal use.

Interpretation

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

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

"the 1971 Act" means the Medicines Act 1971;

"assistance in connection with a mutual recognition application" means the preparation of an assessment report of the type required by virtue of the second paragraph of Article 17.3 of Directive 81/851/EEC in order for an application to be made to a member State for mutual recognition of a marketing authorisation, or the updating of an existing assessment report for the purpose of enabling such an application to be made, and includes any assistance given of the type specified in Articles 18.2 and 18.3 of that Directive in connection with the application for mutual recognition in relation to which the assessment report or updated assessment report has been prepared;

"Directive 81/851/EEC" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**2**) as amended by Council Directives 90/676/EEC(**3**) and 93/40/EEC(**4**) and as extended by Directive 90/677/EEC(**5**) and widened by Directive 92/74/EEC(**6**);

"Directive 90/677/EEC" means Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products;

"Directive 92/74/EEC" means Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homoeopathic veterinary medicinal products;

(**1**) 1968 c. 67.
(**2**) OJ No. L317, 6.11.81, p.1.
(**3**) OJ No. L373, 31.12.90, p.15.
(**4**) OJ No. L214, 24.8.93, p.31.
(**5**) OJ No. L373, 31.12.90, p.26.
(**6**) OJ No. L297, 13.10.92, p.12.

"EEA Agreement" means the Agreement on the European Economic Area(**7**) signed at Oporto on 2nd May 1992 as adjusted by the Protocol(**8**) signed at Brussels on 17th March 1993 and as amended by the Decision of the EEA Joint Committee No. 7/94(**9**);

"EEA State" means a State which is a Contracting Party to the EEA Agreement other than the United Kingdom;

"marketing authorisation" means an authorisation to place on the market in the United Kingdom a Veterinary Medicinal Product but does not include a marketing authorisation granted by the Community in accordance with the provisions of Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**10**);

"the Ministers" has the meaning given by regulation 1(4) of the 1994 Regulations;

"pay", when used in the context of a requirement, means pay subject to any exception, waiver or reduction provided for in these Regulations, and related expressions shall be construed accordingly;

"product" means a medicinal product as defined in the 1971 Act save that–

(a) it includes–

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

(ii) any Veterinary Medicinal Product which would not otherwise count as a medicinal product, and

(b) it excludes medicated feedingstuffs.

"Regulation (EC) No. 541/95" means Commission Regulation (EC) No. 541/95 concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a Member State(**11**);

"the 1994 Regulations" means the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**12**);

"the 1997 Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1997(**13**);

"relevant authority" insofar as it is used in relation to a marketing authorisation, or an application for, or relating to, such an authorisation, means the Ministers, and otherwise means the licensing authority;

"third country" means a country other than an EEA State or the United Kingdom;

"variation with extras", in respect of a marketing authorisation, means changes falling within Annex II to Regulation (EC) No. 541/95;

"Veterinary Medicinal Product" means a veterinary medicinal product of the type specified in Article 1.2 of Directive 81/851/EEC and to which the provisions of that Directive apply; and

"Veterinary Products Committee" means the committee established by the Medicines (Veterinary Products Committee) Order 1970(**14**).

(**7**) OJ No. L1, 3.1.94, p.3.
(**8**) OJ No. L1, 3.1.94, p.572.
(**9**) OJ No. L160, 28.6.94, p.1.
(**10**) OJ No. L214, 24.8.93, p.1.
(**11**) OJ No. L55, 11.3.95, p.7.
(**12**) S.I.1994/3142 to which there are amendments not relevant to these Regulations.
(**13**) S.I. 1997/1469.
(**14**) S.I. 1970/1304.

(2) Other expressions used in these Regulations have, in so far as the context admits, the same meanings as in Directive 81/851/EEC, Regulation (EC) No. 541/95, the Act and the 1971 Act.

(3) In these Regulations, unless the context otherwise requires–

(a) any reference to a numbered regulation or to a numbered Schedule is a reference to the regulation of or the Schedule to these Regulations so numbered in these Regulations;

(b) any reference in a regulation or a Schedule or Part of a Schedule to a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule or Part of a Schedule in which the reference occurs; and

(c) any reference in a Schedule or Part of a Schedule to a lettered table is a reference to the table so lettered in the Schedule or Part of a Schedule in which the reference occurs.

(4) Part I of Schedule 1 shall have effect for the purpose of the interpretation of Schedule 1.

Applications for the grant of marketing authorisations, product licences, manufacturer's licences, wholesale dealer's licences and animal test certificates

3.—(1) Where a person applies for the grant of a marketing authorisation, a product licence, a manufacturer's licence, a wholesaler dealer's licence, or an animal test certificate, he shall pay the relevant fee prescribed in Part II of Schedule 1.

(2) Paragraph (1) shall not be taken to impose any obligation on an applicant for a new marketing authorisation or product licence falling within regulation 11(2), or on an applicant for a variation with extras.

Applications for assistance in connection with mutual recognition

4. Where a person applies for assistance in connection with a mutual recognition application, he shall pay the relevant fee prescribed in Part III of Schedule 1.

Applications for variation of marketing authorisations, product licences, manufacturer's licences, wholesale dealer's licences and animal test certificates

5.—(1) Where a person applies to vary a marketing authorisation, a product licence, a manufacturer's licence, a wholesale dealer's licence or an animal test certificate, he shall pay the relevant fee prescribed in Part IV of Schedule 1.

(2) This regulation extends to applications for a variation with extras.

Multiple variations

6. Where a person applies to vary a provision of a marketing authorisation, licence or certificate, no fee is payable in respect of any variation which is consequential upon another variation of a provision of the same marketing authorisation, licence or certificate applied for in the same application.

Variation at the invitation of the relevant authority

7. No fee is payable for a variation made at the express written invitation of the relevant authority.

Applications for renewal of marketing authorisations, product licences, manufacturers' licences and animal test certificates

8. Where a person applies–

(a) for the renewal of a marketing authorisation, a product licence, a manufacturer's licence or an animal test certificate, or

(b) for a new marketing authorisation or product licence falling within regulation 11(2),

he shall pay the relevant fee prescribed in Part V of Schedule 1.

Applications for renewal of marketing authorisations, product licences, manufacturer's licences and animal test certificates in terms which are not identical to the existing marketing authorisation, licence or certificate

9. Where a person applies for renewal of a marketing authorisation, a product licence, a manufacturer's licence or an animal test certificate so as to contain variations (that is to say provisions which are not identical to those contained in that marketing authorisation, licence or certificate as in force at the date of that application), he shall pay the fee payable pursuant to regulation 8 plus the fee which would have been payable had the application been an application to vary the authorisation, licence or certificate in question.

Site inspections

10.—(1) Where the relevant authority carries out any inspection in connection with an application for the grant, variation or renewal of a manufacturer's licence the applicant shall pay the relevant fee prescribed in Schedule 2.

(2) The holder of a manufacturer's licence shall pay the relevant fee prescribed in Schedule 2 in respect of any other inspection by the relevant authority of a site relating to that licence.

(3) Where a manufacturing site in a third country is specified in a marketing authorisation or product licence, and the site is inspected by the relevant authority, the marketing authorisation or product licence holder shall pay the relevant fee prescribed in Schedule 2; and if there is more than one marketing authorisation or product licence in which the site in question is specified, liability to pay the relevant fee prescribed in Schedule 2 shall be divided between the holders of the marketing authorisations or product licences, as the case may be, in proportion to the number of marketing authorisations or product licences held for products manufactured at that site.

(4) No fee is payable in respect of any inspection of a site carried out within 6 months of a previous inspection in order to ascertain whether an alteration or improvement to premises on that site, which was required in writing by the relevant authority as the result of that previous inspection, has been implemented.

Marketing authorisations and product licences: annual fees

11.—(1) The holder of any marketing authorisation or product licence shall, following each calendar year during which or part of which any product to which the marketing authorisation or product licence relates has been sold, supplied or manufactured, pay an annual fee calculated in accordance with Schedules 3 and 4 in respect of that year.

(2) Where, during the course of the calendar year in question, a new marketing authorisation or product licence has been granted as part of an arrangement involving the termination of a previous marketing authorisation or product licence in respect of a product the characteristics of which are identical to that of the product covered by the new authorisation or licence, any sale, supply or manufacture of a product covered by the previous authorisation or licence shall for the purposes of paragraph (1) be treated as covered by the new authorisation or licence.

Manufacturer's licences: annual fees

12. The holder of a manufacturer's licence, other than one specified in paragraph 6(2) of Part II of Schedule 1, shall pay an annual fee of £190 following each anniversary of the grant of the licence.

Wholesale dealer's licences: annual fees

13.—(1) The holder of a wholesale dealer's licence, other than one specified in paragraph (2), shall pay an annual fee of £380 following each anniversary of the grant of the licence.

(2) In the case of the holder of a wholesale dealer's licence who has a turnover in products of less than £40,000 the annual fee for such a licence, if the payment is accompanied by a declaration certifying that turnover, is £185 and shall be payable following each anniversary of the grant of the licence.

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

Registration of Homoeopathic Veterinary Medicinal Products

14.—(1) A person who applies to the Ministers to register a product shall pay the relevant fee prescribed in Part II of Schedule 5.

(2) A person who applies to the Ministers to renew the registration of a product shall pay a fee of £75.

(3) A person who applies to the Ministers for authorisation to alter an Article 8 dossier relating to a registered product shall pay a fee of £85.

(4) No fee is payable in connection with an application for the registration of a product, for the renewal of a registration of a registered product, or for the authorisation to alter an Article 8 dossier relating to a registered product, which is made at the express written invitation of the Ministers.

(5) The Ministers shall waive or refund payment of any fee otherwise payable under paragraph (1) in the circumstances and to the extent specified in Part III of Schedule 5.

(6) For the purposes of this regulation and Schedule 5 the terms–

"Article 8 dossier";

"the Board";

"the Ministers";

"product"; and

"registered",

shall have the meanings respectively given to such terms by regulation 2(1) of the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(**15**), as read, in the case of the expression "the Ministers", with regulation 2(5) of those Regulations, and related expressions shall be construed accordingly.

(7) Part I of Schedule 5 shall have effect for the purpose of the interpretation of Schedule 5.

Marketing authorisations, product licences and animal test certificates: fees for references to the Veterinary Products Committee or to the Medicines Commission

15. In respect of any reference to the Veterinary Products Committee or to the Medicines Commission–

(**15**) S.I. 1997/322.

(a) notified to an applicant under section 21 of the Act in connection with his application for the grant or renewal of a product licence or under that section as adapted by section 38 of the Act in connection with his application for the grant or renewal of an animal test certificate; or

(b) in relation to which notification is given to an applicant under the 1994 Regulations in connection with his application for the grant or renewal of a marketing authorisation,

the applicant shall pay, within 14 days following notice of the reference being sent to him, the relevant fee prescribed in Schedule 6.

Payment of fees

16.—(1) Subject to paragraph (2), any fee payable under these Regulations shall be payable to the Minister of Agriculture, Fisheries and Food.

(2) A fee payable under regulation 12 or 13 in relation to a manufacturer's licence or wholesale dealer's licence (and a fee payable in relation to any inspection carried out in connection with any such licence) shall be payable to the Secretary of State or the Minister of Agriculture, Fisheries and Food as may be indicated on the written notice requiring payment referred to in regulation 17(2).

(3) Any unpaid sum due under these Regulations by way of any fee shall be recoverable as a debt.

Time for payment of fees

17.—(1) Subject to regulation 15 and paragraphs (2) and (3)(b), any fee payable under these Regulations in connection with any application shall be payable at the time of that application.

(2) A fee payable under regulation 11, 12 or 13 or any fee for an inspection made either in connection with an application or during the currency of a marketing authorisation or licence shall be payable within 30 days from and including the date of written notice requiring payment of the fee being sent by post by the relevant authority to the person by whom the fee is payable.

(3) If, for the purposes of processing or provision of assistance in connection with an application or carrying out an inspection, a particular fee has been paid and, following the determination of the application, completion of the provision of assistance or the inspection, it becomes apparent that–

(a) a lesser fee was properly payable, the excess shall be refunded to that person; or

(b) a higher fee was properly payable, the balance due shall be payable within 30 days from and including the date of the written notice requiring payment of the balance being sent by post by the relevant authority to that person.

(4) The relevant authority need not and to the extent required by Regulation (EC) No. 541/95 shall not process an application in connection with–

(a) a marketing authorisation, or

(b) a manufacturer's or wholesale dealer's licence relating to products to which Directive 81/851/EEC applies,

until receipt of the appropriate fee, unless the application is a relevant variation application.

(5) In the case of any relevant variation application relating to such an authorisation or licence, the relevant authority–

(a) may by notice sent to the applicant specify the difference between the appropriate fee payable and the fee paid by the applicant, explain the reason for the difference and stipulate that, if the difference in question is not paid to the relevant authority by such a date as is specified in the notice (being at least 14 days after the date that the notice is sent), the application may not be further processed, and

(b) if that difference is not paid, need not continue to process the application once the time specified for payment of that difference in the notice has expired, until receipt of that payment.

(6) In relation to any application to which regulation 14 applies, paragraph (4) shall apply as if the application were an application (not being a relevant variation application) relating to a marketing authorisation and the Ministers (as defined in regulation 14) were the relevant authority.

(7) For the purposes of paragraph (4), "relevant variation application" means any application falling within paragraph (b) of the definition of "individual variation" in Part I of Schedule 1 in relation to which a fee has been paid which is based on the applicant's assessment of the fee payable but is less than the appropriate fee for the application.

Late payment of annual fees

18.—(1) Where a person fails to pay the annual fee or any part of such fee for a marketing authorisation or product licence within 30 days from and including the due date, he shall pay an additional fee equivalent–

(a) where payment is received by the relevant authority after 30 but before 60 days have expired from and including the due date, to 1% of the annual fee payable;

(b) where payment is received by the relevant authority after 60 but before 90 days have expired from and including the due date, to 2% of the annual fee payable; and

(c) where payment has not been received by the relevant authority after the expiry of 90 days, to 5% of the annual fee payable.

(2) In calculating the sum due under paragraph (1) the additional fee payable shall in all cases be rounded up to the nearest £10.

(3) Where the person to whom regulation 11(1) applies 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 by him cannot be determined before the due date, he may make a payment of an amount on account of the annual fee payable by him.

(4) Where a person to whom regulation 11(1) applies has made a payment on account in the circumstances mentioned in paragraph (3), any additional fee payable by him under this regulation shall be calculated as if, in paragraph (1) above, the reference to the annual fee payable were a reference to the difference between the payment on account and the amount of the annual fee as subsequently determined.

(5) In this regulation, "due date" means the date of the written notice sent in accordance with regulation 17(2).

Suspension of licences and certificates

19.—(1) Where any sum payable under these Regulations remains unpaid by the holder of a licence or certificate, the relevant authority may send notice to him by post 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 relevant authority may allow, the said sum remains unpaid, the relevant authority may forthwith suspend the licence or certificate until such sum has been paid.

(2) In paragraph (1), "licence" does not include a manufacturer's or wholesale dealer's licence relating to products to which Directive 81/851/EEC applies.

Waiver, reduction or refund of fees

20. The relevant 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–

(a) in any of the circumstances specified in paragraphs 1 to 3 of Schedule 7, or

(b) on an individual application for such waiver, reduction or refund, if the relevant authority concludes that exceptional circumstances justify the waiver, reduction or refund in question,

and shall do so in the circumstances specified in paragraph 4 of Schedule 7.

Revocation

21. Subject to regulation 22, the 1997 Regulations are hereby revoked.

Transitional provisions

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

(2) A fee shall be payable in respect of any inspection made, 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, in connection with an application to renew a marketing authorisation, licence or certificate made under the 1997 Regulations, the authorisation, licence or certificate is due to expire on or after the date these Regulations come into force, regulation 17(4) and (5) shall apply to that application as if the fee payable for the equivalent application under these Regulations were the appropriate fee payable.

(4) Nothing in these Regulations shall have effect in relation to an annual fee relating to a calendar year earlier than 1997.

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State,
24th September 1998 Department of Health

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State, Welsh
25th September 1998 Office

Sewel
Parliamentary Under Secretary of State, Scottish
25th September 1998 Office

Nick Brown
29th September 1998 Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 24th day of September 1998

L.S.

D.C. Gowdy
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 28th day of September 1998

L.S.

P. Small
Permanent Secretary

We consent,

Clive Betts
Jim Dowd
Two of the Lords Commissioners of Her
25th September 1998 Majesty's Treasury