STATUTORY INSTRUMENTS

1998 No. 2428

MEDICINES

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

Made - - - -	*29th September 1998*
Laid before Parliament	*8th October 1998*
Coming into force - -	*1st November 1998*

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), (2) and (3)(b) 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**), and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated(**4**) for the purpose of section 2(2) of the European Communities Act 1972(**5**) in relation to medicinal products and the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

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.

(**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 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.

(**4**) S.I. 1972/1811.

(**5**) 1972 c. 68.

Interpretation

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

"the Act" means the Medicines Act 1968(**6**);

"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(**7**) as amended by Council Directives 90/676/EEC(**8**) and 93/40/EEC(**9**) and as extended by Directive 90/677/EEC(**10**) and widened by Directive 92/74/EEC(**11**);

"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;

"EEA Agreement" means the Agreement on the European Economic Area(**12**) signed at Oporto on 2nd May 1992 as adjusted by the Protocol(**13**) signed at Brussels on 17th March 1993 and as amended by the Decision of the EEA Joint Committee No. 7/94(**14**);

"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(**15**);

"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–

(**6**) 1968 c. 67.
(**7**) OJ No. L317, 6.11.81, p.1.
(**8**) OJ No. L373, 31.12.90, p.15.
(**9**) OJ No. L214, 24.8.93, p.31.
(**10**) OJ No. L373, 31.12.90, p.26.
(**11**) OJ No. L297, 13.10.92, p.12.
(**12**) OJ No. L1, 3.1.94, p.3.
(**13**) OJ No. L1, 3.1.94, p.572.
(**14**) OJ No. L160, 28.6.94, p.1.
(**15**) OJ No. L214, 24.8.93, p.1.

(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(**16**);

"the 1994 Regulations" means the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**17**);

"the 1997 Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1997(**18**);

"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(**19**).

(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.

(**16**) OJ No. L55, 11.3.95, p.7.
(**17**) S.I. 1994/3142 to which there are amendments not relevant to these Regulations.
(**18**) S.I. 1997/1469.
(**19**) S.I. 1970/1304.

(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(**20**), 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–

(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

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

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 Majesty's Treasury

25th September 1998

SCHEDULE 1 Regulations 2(4), 3, 4, 5, 8 and 12

FEES RELATING TO APPLICATIONS FOR THE GRANT, VARIATION AND RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

PART I

INTERPRETATION

In this Schedule, unless the context requires otherwise–

"abridged standard application" means an application for a marketing authorisation which, by virtue of regulation 4(8) of the 1994 Regulations, need not be accompanied by the results of tests and trials of the type specified in Article 5.10 of Directive 81/851/EEC but does not include a simple application or an emergency vaccine application;

"active ingredient" means the ingredient of a product in respect of which efficacy is claimed in an application to which this Schedule relates;

"application for a type A marketing authorisation" means an application for a marketing authorisation to which regulation 5(a) of the 1994 Regulations applies;

"application for a type B marketing authorisation" means an application for a marketing authorisation to which regulation 5(b) of the 1994 Regulations applies;

"Article 15.2 marketing authorisation" means a marketing authorisation of the type specified in Article 15.2 of Directive 81/851/EEC;

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

"Category I application" means an application for assistance in connection with a mutual recognition application other than a Category II or III application;

"Category II application" means an application, other than a Category III application, for assistance in connection with a mutual recognition application relating to a marketing authorisation granted in respect of a Veterinary Medicinal Product only intended for administration to animals whose flesh or products are not intended for human consumption;

"Category III application" means an application for assistance in connection with a mutual recognition application relating to a marketing authorisation granted in respect of an immunological Veterinary Medicinal Product;

"complex application" means an application for, or for a variation of, a marketing authorisation or product licence where the application–

(a) relates to a product which is intended to be used–

  (i) in accordance with an indication for use in respect of a species of animal, or

  (ii) as a treatment for a medicinal purpose,

  for which it has not previously been used;

(b) relates to a product containing a combination of active ingredients which have not previously been included in that combination in a product in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(c) relates to a product containing a new excipient;

(d) relates to a product which is intended to be administered by a route of administration different from that used in the administration of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or a product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(e) relates to a sterile product the manufacture of which involves a method of sterilisation different from that used in the manufacture of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(f) relates to a product containing an active ingredient the manufacture of which involves a route of synthesis (or, in the case of a product not synthetically produced, a method of manufacture) different from that used in the manufacture of the active ingredient of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(g) relates to a biological 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 product–

(i) which contains the same active ingredient as the product in question and

(ii) in respect of which a marketing authorisation or product licence has previously been granted in the United Kingdom;

(h) relates to a product which is a controlled release preparation in circumstances where a marketing authorisation or product licence for animal use (other than a product licence of right) for such a preparation constituting the same active ingredient as the product in question has not previously been granted in the United Kingdom;

(i) relates to a sterile product (the container of which is directly in contact with the product) which is made from a material different from that used for the container of any product–

(i) which contains the same ingredient as the product in question and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom;

(j) names as manufacturer of the active ingredient of the product in question a manufacturer different from the manufacturer of the active ingredient of any product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted in the United Kingdom; or

(k) relates to a biological 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 product–

(i) which contains the same active ingredient as the product in question, and

(ii) in respect of which a marketing authorisation or product licence has previously been granted in the United Kingdom, but does not include a major application or an emergency vaccine application;

"emergency vaccine" means a vaccine 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 authorised or licensed vaccines are readily available for such use;

"emergency vaccine application" means an application, limited to use of an emergency vaccine, for a marketing authorisation or product licence;

"excipient", in relation to an immunological Veterinary Medicinal Product, includes an adjuvant;

"food-producing animals" means animals whose flesh or products are intended for human consumption;

"immunological Veterinary Medicinal Product" has the same meaning as in Directive 90/677/EEC;

"individual variation" means, in relation to an application to vary (or renew with variations)–

(a) a mutually recognised marketing authorisation, a variation covered by any single numbered paragraph of Annex I to Regulation (EC) No. 541/95; and

(b) any other authorisation or licence or certificate, any element in the application which calls for a separate assessment in order to reach a decision whether the application should be granted; "marketing authorisation (parallel import)" means a marketing authorisation granted by the Ministers in respect of a Veterinary Medicinal Product–

(c) which is imported into the United Kingdom from an EEA State,

(d) for which there has been granted a marketing authorisation by an EEA State, and

(e) which has no therapeutic effect different from that of a Veterinary Medicinal Product for which a marketing authorisation has already been granted in the United Kingdom;

"major application" means an application for a marketing authorisation or product licence in respect of a product containing a new active ingredient but does not include an emergency vaccine application;

"member State" means a member State other than the United Kingdom;

"mutually recognised marketing authorisation" means a marketing authorisation which has been mutually recognised by a member State;

"new active ingredient" means–

(a) an active ingredient that has not previously been included as an active ingredient in a product in respect of which a marketing authorisation or 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 product where the product is derived from genetically engineered micro-organisms, recombinant DNA technology or monoclonal antibodies; or

(c) in the case of a biological product, a vaccine of a particular micro-organism whether in a live or inactivated form, other than 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 product in respect of which a marketing authorisation or product licence (not being a product licence of right) has previously been granted in the United Kingdom;

"new excipient", in relation to a product containing it, means any ingredient which–

(a) is not an active ingredient,

(b) has not previously been included in a product of a different description–

(i) which is intended to be administered by the same route of administration as that of the product containing it; and

(ii) in respect of which a marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted, and

(c) if the product containing it is intended to be administered orally, is not specified in any Act or subordinate legislation as able to be used lawfully as an ingredient of or additive for–

(i) food for human consumption in any event; or

(ii) animal feedingstuffs, in any case where the product containing it is intended for administration after being incorporated in an animal feedingstuff;

"Reference Member State" has the meaning given by Article 2.2 of Regulation (EC) No. 541/95;

"simple application" means an application for a marketing authorisation or 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 marketing authorisation or product licence for animal use (other than a product licence of right) has previously been granted;

(b) is made with the permission of the marketing authorisation or licence holder for the existing product; and

(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; and

(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;

but does not include an emergency vaccine application.

"standard application" means an application which is not a major, complex, abridged standard or simple application;

"Type I variation–Administrative" means a variation of a type listed in variations 2 and 3 of Annex I to Regulation (EC) No. 541/95;

"Type I variation–Scientific" means a variation of a type listed in variations 1 and 4 to 33 of Annex 1 to Regulation (EC) No. 541/95;

"Type I variation, Scientific–Type II procedure" means a variation within the derogation, insofar as it relates to products falling within the scope of Directive 90/677/EEC, in introductory statement A of Annex 1 to Regulation (EC) No. 541/95; and

"Type II variation" means a variation of the type referred to in Article 3.1(b) of Regulation (EC) No. 541/95.

PART II

FEES RELATING TO APPLICATIONS FOR THE GRANT OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations and product licences

1. Subject to paragraphs 2, 3, 4 and 5–

(a) the fee for an application for a type A marketing authorisation of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (2) of that Table;

(b) the fee for an application for a type B marketing authorisation of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (3) of that Table; and

(c) the fee for an application for a product licence of a kind described in an entry in column (1) of Table A is the fee specified in the corresponding entry in column (4) of that Table.

Table A

Column (1) *Kind of application*	*Column (2)* *Fee for an application for a type A marketing authorisation*	*Column (3)* *Fee for an application for a type B marketing authorisation*	*Column (4)* *Fee for an application for a product licence*
Major application	£18,120	£10,000	£18,120
Complex application	£10,515	£6,000	£10,515
Standard application	£4,540	£3,000	£4,540
Abridged standard application	£3,545	—	—
Simple application	£1,260	£800	£1,260
Emergency vaccine application	£40	—	£40

2. The fee for an application for an Article 15.2 marketing authorisation of a kind described in an entry in column (1) of Table B is the fee specified in the corresponding entry in column (2) of that Table.

Table B

Column (1) *Kind of application*	*Column (2)* *Fee for an application for an Article 15.2 marketing authorisation*
Major application	£10,515
Complex application	£4,540

3. Where an application for a marketing authorisation is made by a person who is already the holder of an Article 15.2 marketing authorisation relating to the same Veterinary Medicinal Product as the marketing authorisation applied for the fee shall be–

(a) where a major application was previously made in respect of the Article 15.2 marketing authorisation, £7,605; and

(b) where a complex application was previously made in respect of the Article 15.2 marketing authorisation, £5,975.

4. 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 product containing the same active ingredient as the product in respect of which the marketing authorisation or 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 (covering export only), relating to the same product as the marketing authorisation or 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.

5.—(1) Subject to sub-paragraphs (2), (3) and (4) below, where an applicant applies in one or more applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or the same combination of active ingredients, the total of the fees payable by him shall equal the aggregate of the amounts payable under paragraph 1 in respect of separate applications for each product licence or type of authorisation.

(2) Subject to sub-paragraphs (3) and (4) below, where an applicant has made an original request (that is to say a set of one or more applications as described in sub-paragraph (1) above) and either–

(a) withdraws each application in the original request and substitutes for them a new application for one or more products containing the same active ingredients or combination of active ingredients as those in the original request, or

(b) withdraws some but not all of the applications in the original request,

then there shall be calculated in respect of the new or (as the case may be) remnant applications the total of the fees which would have been charged for them had they alone comprised the original request, and that total shall be payable in respect of the new or (as the case may be) remnant applications, but there shall be allowed against it the net total of any fees payable in respect of the original request (that is to say the total so payable less any amount of that total waived, reduced or refunded under these Regulations).

(3) Where an applicant applies in one or more major applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or combination of active ingredients the fee payable for each major application for a marketing authorisation or product licence shall be the amount payable in respect of a major application under paragraph 1 in respect of the first major application and for each major application additional to the first–

(a) which relates to a product of a different dosage form, the amount payable in respect of a complex application under paragraph 1; and

(b) which relates to a product of the same dosage form but of a different strength of any active ingredient, the amount payable in respect of a standard application under paragraph 1.

(4) Where an applicant applies in one or more complex applications, which are all pending, for a marketing authorisation or product licence for more than one product and each product contains the same active ingredient or combination of active ingredients, the fee payable for each complex

application for a marketing authorisation or product licence shall be the amount payable in respect of a complex application under paragraph 1 in respect of the first complex application, and for each complex application additional to the first–

(a) which relates to a product of a different dosage form, the amount payable in respect of a standard application under paragraph 1; and

(b) which relates to a product of the same dosage form but of a different strength of any active ingredient, the amount payable in respect of a simple application under paragraph 1.

(5) This paragraph applies in relation to fees which would, but for this paragraph, be payable by reference to paragraph 1, whether or not as qualified by paragraph 4.

Manufacturer's licences

6.—(1) The fee for an application for a manufacturer's licence shall be–

(a) in a case to which sub-paragraph (2) below applies, £95; or

(b) in any other case £2,040; 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) This paragraph applies in the case of an application for a manufacturer's licence which is limited solely to the manufacture or assembly of–

(a) products the sale or supply of which do not require a marketing authorisation or product licence and to which article 2(2)(i) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**21**) applies; or

(b) emergency vaccines.

Wholesale dealer's licences

7.—(1) Subject to the following provision of this paragraph, the fee for an application for a wholesale dealer's licence is £1,185.

(2) Where an applicant for a wholesale dealer's licence anticipates that his turnover in his first calendar year of trading will be less than £40,000, he may pay a provisional fee of £480 if his payment is accompanied by an estimate of such turnover for that year, which shall, subject to the following provisions of this paragraph, be crystallised as his final fee for his application.

(3) Following the first anniversary of the grant of a wholesale dealer's licence, where a wholesale dealer has sent with his application for a wholesale dealer's licence such an estimate of turnover for his first calendar year of trading, he shall, together with his payment of the annual fee payable pursuant to regulation 13(1), send a declaration certifying his turnover for his first calendar year of trading.

(4) If either a declaration, as required by sub-paragraph (3) above, is not sent or the declaration, sent in accordance with sub-paragraph (3) above, shows that the wholesale dealer's turnover for his first calendar year of trading was £40,000 or more, the wholesale dealer shall pay the balance in accordance with regulation 17(3)(b).

(5) Where a wholesale dealer has paid the full fee specified in sub-paragraph (1) above but his turnover for his first calendar year of trading was less than £40,000, if he sends a declaration certifying that turnover, the relevant authority shall refund the excess in accordance with regulation 17(3)(a).

(6) For the purposes of this paragraph, "turnover" has the same meaning as in regulation 13, "trading" means trading as a wholesale dealer, and "balance" and "excess" both mean the difference

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

between the sum payable under sub-paragraph (1) and the sum payable under sub-paragraph (2) above.

Animal test certificates

8. The fee for an application for an animal test certificate in relation to a product which is a biological product or is for administration to non food-producing animals is £250, and for any other application for an animal test certificate is £600.

Marketing authorisation (parallel import)

9. The fee for an application for a marketing authorisation (parallel import) is £1,415.

PART III

FEES RELATING TO APPLICATIONS FOR ASSISTANCE IN CONNECTION WITH MUTUAL RECOGNITION APPLICATIONS

1. Subject to paragraphs 3 and 4, where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to not more than five member States, the fee for such application shall be the fee specified in the corresponding entry in column (2) of that Table.

2. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to more than five member States, the fee for such application shall be the fee specified in the corresponding entry in column (2) of Table C, plus the additional fee specified in the corresponding entry in column (3) of that Table for the sixth and each additional member State.

3. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and an application for such assistance in respect of the same authorisation has previously been made by the applicant, no fee shall be payable in respect of the new application if the total number of member States to which the previous application and the new application relate does not exceed five.

4. Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table C is made within six months after the grant of the marketing authorisation to which it relates, and

(a) an application for such assistance in respect of the same authorisation has previously been made by the applicant; and

(b) the total number of member States to which the previous application related exceeds five,

the fee in column (3) of Table C shall be payable for the sixth and each additional member State exceeding five to which the new application relates.

Table C

Column (1) *Kind of application*	*Column (2)* *Basic fee*	*Column (3)* *Additional Fee for the sixth and each additional member State*
Major	£3,250	£700
Complex	£2,175	£340
Standard	£940	£175
Simple	£315	£60

5.—(1) Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to not more than five member States, the fee for such application shall, subject to sub-paragraph (3) below, be the fee specified in the corresponding entry in column (2) of Table D.

(2) Where an application for assistance in connection with a mutual recognition application of a kind described in an entry in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and such application relates to an application for mutual recognition to be made to more than five member States, the fee for such application shall, subject to sub-paragraph (3) below, be the fee specified in the corresponding entry in column (2) of Table D plus, for the sixth and each additional member State, the fee specified in the corresponding entry in column (3) of that Table.

(3) Where an application for assistance in connection with a mutual recognition application of a kind described in column (1) of Table D is made more than six months after the grant of the marketing authorisation to which it relates, and an application for such assistance in respect of the same authorisation has previously been made by the applicant, the fee specified in the corresponding entry in column (3) of Table D shall be payable for each additional member State which was not covered by the previous application.

Table D

Column (1) *Kind of application*	*Column (2)* *Basic fee*	*Column (3)* *Additional fee for the sixth and each additional member State*
Category I application	£7,975	£1,000
Category II application	£5,320	£665
Category III application	£4,255	£530

PART IV

FEES RELATING TO APPLICATIONS FOR THE VARIATION OF MARKETING AUTHORISATIONS, PRODUCT

LICENCES, MANUFACTURER'S LICENCES, WHOLESALE DEALER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations (other than mutually recognised marketing authorisations) and product licences

1. The fee for a complex application for the variation of–

(a) a marketing authorisation, other than a mutually recognised marketing authorisation, or

(b) a product licence,

is £2,000 in respect of each individual variation.

2. The fee for an application of a kind described in an entry in column (1) of Table E for the variation of–

(a) a marketing authorisation, other than a mutually recognised marketing authorisation; or

(b) a product licence,

other than a complex application, is that specified in the corresponding entry in column (2) of that Table.

Table E

Column (1) *Kind of application*	*Column (2)* *Fee*
Variation requiring veterinary, scientific or pharmaceutical assessment (where the authorisation or licence is not related solely to an emergency vaccine)	£500 for each individual variation in that application plus £200 for each additional consequential individual variation to other authorisations or licences in identical terms
Variation not requiring veterinary, scientific or pharmaceutical assessment (where the authorisation or licence is not related solely to an emergency vaccine)	£200 in respect of each individual variation
Variation where the authorisation or licence relates solely to an emergency vaccine	£40 in respect of each individual variation

Mutually recognised marketing authorisations

3. Subject to paragraph 4, the fee for an application for the variation (of a kind described in an entry in column (1) of Table F) of a mutually recognised marketing authorisation shall, in respect of each individual variation to which the application relates, be that specified in the corresponding entry in column (2) of that Table where the United Kingdom is acting as the Reference Member State and that specified in the corresponding entry in column (3) of the said Table where the United Kingdom is not acting as the Reference Member State–

Table F

Column (1) *Kind of application*	*Column (2)* *Fee–United Kingdom acting as the Reference Member State*	*Column (3)* *Fee–United Kingdom not acting as the Reference Member State*
Type I variation—Administrative	£530	£100
Type I variation—Scientific	£2,130	£500
Type I variation, Scientific—Type II procedure	£3,500	£1,000
Type II variation	£7,445	£2,000
Variation with extras	£8,510	£3,560

4. The fee for an application for a connected variation, that is to say a variation (of a kind described in an entry in column (1) of Table F) of a mutually recognised marketing authorisation which is consequential on, additional and in identical terms to an actual or proposed variation of another such authorisation covered both by the same applicant and by a fee paid in pursuance of paragraph 3 shall, in respect of each connected variation to which the application relates, be £530 per individual variation where the United Kingdom is acting as the Reference Member State and £100 per individual variation where the United Kingdom is not acting as Reference Member State.

Manufacturer's licences

5. The fee for an application for the variation of a manufacturer's licence–

(a) in the case of a manufacturer's licence referred to in paragraph 6(2) of Part II of this Schedule, is £95, and

(b) in any other case–

(i) requiring veterinary, scientific or pharmaceutical assessment, is £360, and

(ii) not requiring veterinary, scientific or pharmaceutical assessment, is £120,

in respect of each individual variation.

Wholesale dealer's licences

6. The fee for an application for the variation of a wholesale dealer's licence–

(a) requiring veterinary, scientific or pharmaceutical assessment, is £360, and

(b) not requiring veterinary, scientific or pharmaceutical assessment, is £120,

in respect of each individual variation.

Animal test certificates

7. The fee for an application for the variation of an animal test certificate is £200 in respect of each individual variation.

PART V

FEES RELATING TO APPLICATIONS FOR THE RENEWAL OF MARKETING AUTHORISATIONS, PRODUCT LICENCES, MANUFACTURER'S LICENCES AND ANIMAL TEST CERTIFICATES

Marketing authorisations and product licences

1. Subject to paragraph 4, the fee for an application for the renewal of a marketing authorisation or product licence (or the grant of such an authorisation or licence in circumstances in which regulation 11(2) applies)–

(a) that relates solely to an emergency vaccine is £40,

(b) that relates to a herbal product is £300, and

(c) in any other case is £900.

Manufacturer's licences

2. The fee for an application for a renewal of a manufacturer's licence referred to in paragraph 6(2) of Part II of this Schedule is £90.

Animal test certificates

3. The fee for an application for renewal of an animal test certificate is £90.

Article 15.2 marketing authorisations

4. Where an Article 15.2 marketing authorisation is renewed, no fee is payable in respect of the first such renewal.

SCHEDULE 2

Regulations 10(1), (2) and (3)

FEES RELATING TO SITE INSPECTIONS

Interpretation

1.—(1) In this Schedule–

"biological product" has the same meaning as set out in Part I of Schedule 1;

"dormant biological product" means a biological 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;

"immunological Veterinary Medicinal Product" has the same meaning as in Part I of Schedule 1;

"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 activity of manufacturing or assembling products and also includes any person whose

connection with that activity involves 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; and

"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 operating partly as a relevant person (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 in so operating or, where such a calculation is inappropriate, by reference to the proportion of his job which can otherwise be reasonably attributed to so operating 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 and 4, except in the case of an inspection falling within sub-paragraphs (2) to (4) below, the fee payable in respect of an inspection of a kind described in an entry in column (1) of Table A is that specified in the corresponding entry in column (2) of that Table.

Table A

Column (1) *Kind of inspection*	*Column (2)* *Fee*
Supersite inspection	£8,390
Major inspection	£4,415
Standard inspection	£3,155
Minor inspection	£1,705

(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 for an inspection of a kind described in an entry in column (1) of Table B of such a site shall be that specified in the corresponding entry in column (2) of that Table.

Table B

Column (1) *Kind of inspection*	*Column (2)* *Fee*
Supersite inspection	£13,905
Major inspection	£7,680
Standard inspection covering immunological Veterinary Medicinal Products	£5,010
Other standard inspection	£3,775
Minor inspection covering immunological Veterinary Medicinal Products	£2,580
Other minor inspection	£2,525

(3) Except in the case of an inspection falling within sub-paragraph (4) below, where the site inspected is concerned only with the assembly of products the fee payable for an inspection of the kind described in an entry in column (1) of Table C of such a site shall be that specified in the corresponding entry in column (2) of that Table.

Table C

Column (1) *Kind of inspection*	*Column (2)* *Fee*
Supersite inspection	£6,090
Major inspection	£4,115
Standard inspection	£2,015
Minor inspection	£1,035

(4) Where the site inspected is limited solely to the manufacture or assembly of–

(a) products, the sale or supply of which do not require a marketing authorisation or product licence and to which article 2(2)(i) 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; or

(c) products covered by paragraph (a) above and vaccines covered by paragraph (b) above, the fee payable shall be £200.

3.—(1) The fee payable for any inspection of either or both of the premises and the procedures for the quality control of a biological product, in respect of which a marketing authorisation or product licence has been granted or applied for, is £1,210 for each such product which is not a dormant biological product.

(2) A fee of £55 is payable for any such inspection in connection with such an authorised or licensed biological product (not being a dormant biological product) for which a marketing authorisation or product licence was granted because it was identical to an existing product.

4.—(1) The fee payable for an inspection at a site outside the United Kingdom shall be increased by an amount equal to the travelling and subsistence costs of one or more inspectors relating to the inspection and any additional costs reasonably incurred by him in respect of that inspection as a result of it being at a site outside the United Kingdom.

(2) The fee payable for 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 one or more inspectors 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).

(3) For the purposes of sub-paragraphs (1) and (2) above, the fees of an interpreter shall be regarded as included among additional costs capable of being reasonably incurred.

SCHEDULE 3 Regulations 11(1) and 18(3)

MARKETING AUTHORISATIONS AND PRODUCT LICENCES: ANNUAL FEES

PART I

Calculation of turnover

1. In relation to the calculation of turnover in products of any marketing authorisation or product licence holder 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 for the products by manufacturers to wholesalers, except to the extent that the products are supplied by manufacturers direct to retailers, in which case it shall mean the prices charged for the products by the manufacturers to the retailers reduced by such sum as, in the opinion of the relevant authority, represents the difference between the prices paid by the retailers and those which could be expected to be charged by the manufacturers to wholesalers according to the practice prevailing during the period in question with regard to such products.

2. To the extent that a marketing authorisation or product licence holder sells or supplies 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 marketing authorisation or product licence holder for those products.

3. For the purpose of calculating any annual fee payable in respect of marketing authorisations and product licences, "turnover" means the gross value at manufacturers' prices of all authorised or licensed 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 marketing authorisation or product licence.

4.—(1) The relevant authority may require a marketing authorisation or product licence holder to furnish an auditor's certificate containing evidence of the amount of the holder's annual turnover.

(2) If within one month of the date by which such certificate is required to be furnished, or such longer period as the relevant authority may allow, the marketing authorisation or product 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 5 of Part II of this Schedule or shall be such lesser sum, based on the relevant authority's estimate of turnover, as the relevant authority shall specify in a notice served on the marketing authorisation or product licence holder.

PART II

CALCULATION OF ANNUAL FEES

1. In the case of a business with a turnover of £2,800,000 or over, the fee payable shall, subject to paragraph 4 and Part III of this Schedule, be £248 for each marketing authorisation or product licence held, plus £17,640 plus 0.42% of annual turnover in excess of £2,800,000.

2. In the case of a business with a turnover of less than £2,800,000, the fee payable shall, subject to paragraph 4 and Part III of this Schedule, be £205 or 0.63% of annual turnover, whichever is the greater, except that a business 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 an annual fee in accordance with this Schedule shall, if it includes or comprises a fee charged on a percentage basis, as the result of the application of paragraph 1 or 2, be rounded up to the nearest £10.

5. If a marketing authorisation or product licence holder does not submit evidence of turnover in relation to the relevant calendar year to the satisfaction of the relevant 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 product in respect of which a marketing authorisation or product licence is held by the authorisation or licence holder.

PART III

CALCULATION OF ANNUAL FEE—EMERGENCY VACCINES

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

SCHEDULE 4 **Regulation 11(1)**

MARKETING AUTHORISATIONS AND PRODUCT LICENCES: ADJUSTMENT OR REFUND OF ANNUAL FEES

1. Where an annual fee calculated in accordance with paragraph 5 of Part II of Schedule 3 has been paid in accordance with regulation 11 of these Regulations and the relevant authority is subsequently satisfied as to the turnover for the relevant calendar year, the difference between the amount so paid and the annual fee calculated in accordance with paragraphs 1 to 4 of the said Part II (if less) may be refunded by the relevant 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 under the provisions of these Regulations.

SCHEDULE 5 **Regulation 14**

FEES RELATING TO APPLICATIONS FOR REGISTRATION OF HOMOEOPATHIC VETERINARY MEDICINAL PRODUCTS

PART I

INTERPRETATION

In this Schedule–

"application" means an application to register a product;

"formulation" means the formulation of a product but does not include the formulation of a homoeopathic stock contained in such a product;

"the Homoeopathics Directive" means Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homoeopathic veterinary medicinal products(**22**) as adapted by the EEA Agreement;

"homoeopathic stock" has the same meaning as in the Homoeopathics Directive;

"identical" means–

(a) in relation to the formulation of a product, identical as regards the requirements in respect of the qualitative composition, preparation and testing;

(b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the tests which it is required to undergo;

"product" includes a series of products which are all dilutions prepared from an identical homoeopathic stock or stocks and each of which has the same pharmaceutical dosage form;

"repeat formulation", in relation to an application, means–

(a) the formulation of a product which is identical to the formulation of a registered product–

(i) which the applicant is responsible for marketing; or

(ii) to which the applicant has been authorised in writing to make reference for the purposes of his application by the person responsible for marketing that product; or

(b) the formulation of a product which is identical to another product in respect of which the applicant has made a simultaneous application;

"repeat stock", in relation to an application, means–

(a) a homoeopathic stock which is used in the preparation of a product (either on its own or in combination with another homoeopathic stock or stocks), and which is identical to another homoeopathic stock which is used (whether on its own or in combination with any other homoeopathic stock or stocks) in the preparation of a registered product–

(i) which the applicant is responsible for marketing; or

(ii) which another person is responsible for marketing and to which the applicant has been authorised in writing to make reference for the purposes of the application by the person (or, if more than one, each of such persons) who supplied information to the Ministers in connection with the application made to register that registered product; or

(b) a homoeopathic stock which is used in the preparation of a product (either on its own or in combination with another homoeopathic stock or stocks), and which is identical to a homoeopathic stock which is used (whether on its own or in combination with any other homoeopathic stock or stocks) in the preparation of a product in respect of which the applicant has made a simultaneous application; and

"simultaneous application" means an application which is made by an applicant at the same time as making another application or applications, and which is the first of such applications to be considered by the Ministers.

(**22**) OJ No. L297, 13.10.92, p.12.

PART II

FEES RELATING TO APPLICATIONS FOR REGISTRATION

1. Subject to paragraph 2, the fee for an application of a kind described in an entry in column (1) of the Table below shall be–

(a) the fee specified in the corresponding entry in column (2) of that Table in the case of a product prepared from not more than 5 homoeopathic stocks; and

(b) the fee specified in the corresponding entry of column (3) of that Table in the case of a product prepared from more than 5 homoeopathic stocks.

Table

Column (1) *Description of application*	*Column (2)* *Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	*Column (3)* *Fees for applications in respect of products prepared from more than 5 homoeopathic stocks*
An application in respect of a product which is both prepared solely from a repeat stock or stocks and is of a repeat formulation	£100	£250
An application in respect of a product which is either– (a) prepared solely from a repeat stock or stocks; or (b) is of a repeat formulation	£300	£450
Any other application	£500	£650

2. Where an application for registration relates to a product–

(a) for which a certificate of registration has been granted in relation to a product which is equivalent to it under Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**23**); or

(b) which is registered or authorised in an EEA State under legislation which implements the provisions of Article 6 of the Homoeopathics Directive in such State,

the fee for such application shall be–

(i) £100 in the case of a product prepared from not more than 5 homoeopathic stocks, and

(ii) £250 in the case of a product prepared from more than 5 homoeopathic stocks.

(**23**) S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482.

PART III

WAIVER OR REFUND OF FEES

1. Subject to paragraph 2, where an application for registration is withdrawn before determination by the Ministers, the following percentage of the fee otherwise payable 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%; and

(b) if veterinary, scientific or pharmaceutical assessment has begun but has not been completed, 50%.

2. If an application for registration is withdrawn either after veterinary, scientific or pharmaceutical assessment has been completed, or following consideration of that application by the Board or by the Medicines Commission, no refund or waiver of the fee payable in connection with that application shall be made.

SCHEDULE 6

Regulation 15

MARKETING AUTHORISATIONS, PRODUCT LICENCES AND ANIMAL TEST CERTIFICATES: FEES FOR REFERENCES TO THE VETERINARY PRODUCTS COMMITTEE OR TO THE MEDICINES COMMISSION

1. The fee payable under regulation 15 for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with an application for a marketing authorisation or licence of the kind described in column (1) of the Table below shall be that specified in the corresponding entry in column (2) of that Table.

Table

Column (1) *Kind of application*	*Column (2)* *Fee*
Major application	£1,420
Complex application	£820
Standard application	£380
Simple application	£140

2. The fee payable under regulation 15 for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with an application for an animal test certificate shall be £495.

3. For the purposes of this Schedule, the terms–

"complex application";

"major application";

"simple application"; and

"standard application"

shall have the meanings respectively given to such terms in Part I of Schedule 1.

SCHEDULE 7

Regulation 20

WAIVER, REDUCTION OR REFUND OF FEES

1. Where the manufacture, assembly, sale or supply of 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 relevant authority may determine that any fees otherwise payable under these Regulations–

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

(b) in respect of any inspection made during the currency of such a marketing authorisation or product 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 relevant 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 marketing authorisation, product licence or certificate to be granted or an inspection to be made; and

(b) the product in respect of which an application for a marketing authorisation, product licence or certificate has been made–

(i) it 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 relevant authority–

(a) is satisfied that the annual turnover (as calculated in accordance with Schedule 3) relating to a particular product during any calendar year of the first five years of the currency of its actual or prospective marketing authorisation or product licence, has not exceeded, or is unlikely to exceed, £40,000; and

(b) is of the opinion that the interests of human or animal health require a marketing authorisation or product licence for the products in question to be granted, varied or renewed (as the case may be),

a fee otherwise payable under these Regulations in connection with an application made during that five year period for a marketing authorisation or product licence or application for a variation or first application for a renewal of such authorisation or product licence in relation to the product or in connection with an inspection in relation to the product during the currency of that authorisation or 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 authorisation or product licence) as established or as anticipated by the relevant authority and the sum of £40,000.

(2) Before a marketing authorisation or product 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 relevant authority of the actual or anticipated amount of annual turnover, in respect of the particular product, in each calendar year of the first five years of the currency of the authorisation or product licence.

(3) Where a reduced fee is determined in accordance with sub-paragraph (1) above at the time of the application on the basis of the estimated likely maximum turnover of the product during the

first five years of the currency of the authorisation or product 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 actual turnover relating to the product in question in any calendar year in the first five years of the currency of the marketing authorisation or product licence exceeds £40,000, the authorisation or product licence holder shall be liable to pay the balance of the full fee otherwise payable under these Regulations within 30 days from and including the date of written notice sent by the relevant authority in accordance with regulation 17(2).

(5) Where any provisional payment on account is made in accordance with sub-paragraph (3) above, the reduced fee shall be recalculated on the basis of actual turnover in accordance with the provisions of sub-paragraph (1) above at the end of five years from the date of the grant of the marketing authorisation or product licence and any difference between the fee so calculated and the provisional payment on account shall be payable by the applicant within 30 days from and including the date of written notice sent by the relevant authority in accordance with regulation 17 or, as the case may be, refunded to the applicant by the relevant authority.

4.—(1) Subject to sub-paragraph (2) below, where an application for a marketing authorisation or product licence or manufacturer's or wholesale dealer's licence is withdrawn before determination by the relevant authority, the relevant authority shall refund, or where no payment has been made, waive the following percentage of the fee otherwise payable (under regulation 3) in connection with that application–

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

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

(c) if, in a case to which paragraph (b) above applies, a request for further information in connection with the application has been made by the relevant authority under section 44(1) of the Act, or under Article 9 of Directive 81/851/EEC as applied by regulation 5 of the 1994 Regulations, 25%,

and, in the case of 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 relevant authority any subsequent reapplication in respect of the same authorisation or licence by the same applicant shall be charged at 50% of the fee otherwise payable under regulation 3.

(2) If an application for a marketing authorisation or product licence is withdrawn either after scientific or veterinary pharmaceutical assessment has been completed or following consideration of that application by the Veterinary Products Committee or by the Medicines Commission, no refund or waiver of the fee payable (under regulation 3 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 revoke and re-enact with modifications the Medicines (Products for Animal Use —Fees) Regulations 1997. As in the case of the 1997 Regulations, they prescribe fees in connection with applications and inspections relating to:

(a) marketing authorisations granted under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S.I.1994/3142);

(b) licences and certificates granted under the Medicines Act 1968 insofar as they apply to medicinal products for animal use; and

(c) the registration of homoeopathic veterinary medicinal products.

In prescribing fees in relation to the 1994 Regulations, these Regulations continue to supplement the 1994 Regulations in implementing Council Directive 93/40/EEC (OJ No. L214, 24.8.93, p.31) which contains amendments to Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p.1).

The average level of fees payable under the Regulations is increased by 10% in comparison with the 1997 Regulations.

The changes in these Regulations include–

(a) the introduction of a separate fee for variations to marketing authorisations which have been mutually recognised and which relate to medicinal products (primarily immunological) falling within the scope of introductory statement A to Annex 1 of Commission Regulation 541/95/EC;

(b) a reduction in the fee payable for a variation which is additional, consequential and in identical terms to the first variation of a mutually recognised marketing authorisation;

(c) a reduction in the fee payable for manufacturers' licences and wholesale dealers' licences.

The Regulations also provide for:

(a) the method and time for payment of fees (regulations 16 to 18);

(b) the suspension of licences and certificates where fees remain unpaid (regulation 19);

(c) the waiver, reduction or refund of fees (regulation 20 and Schedule 7); and

(d) transitional provisions (regulation 22).

A Regulatory Impact Assessment has been prepared and a copy has been placed in the library of each House of Parliament. Copies may be obtained from the Veterinary Medicines Directorate, Woodham Lane, Addlestone, Surrey, KT15 3LS.