STATUTORY INSTRUMENTS

# 2004 No.2750

# MEDICINES

## The Medicines (Products for Animal Use—Fees) Regulations 2004

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| *Made - - - -* | *21st October 2004* |
| *Laid before Parliament* | *26th October 2004* |
| *Coming into force - -* | *17th November 2004* |

The Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, with the consent of the Treasury, in exercise of the powers conferred upon them by section 1(1), (2) and (3)(b) of the Medicines Act 1971(**a**) and now vested in them(**b**);

And the Secretary of State, being designated for the purposes of section 2(2) of the European Communities Act 1972(**c**) in relation to medicinal products(**d**), in exercise of the powers conferred on her by that section;

And in exercise of the powers conferred by section 56 of the Finance Act 1973(**e**), and with the consent of the Treasury;

After carrying out a consultation with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of the Medicines Act 1968(**f**);

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(**a**) 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 Medicines Act 1971 expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) (see the following footnote).

(**b**) "The Ministers" is defined in section 1(1) of the Medicines Act 1968 (following amendment by article 5(1) and paragraph 15(3) of Schedule 1 to the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794)) as the Secretary of State acting jointly with the Ministers for Northern Ireland specified in paragraphs (a) and (b) of section 1(1) namely the Minister of Health and Social Services for Northern Ireland and the Minister of Agriculture for Northern Ireland. Section 95(5) of and paragraph 10(1)(b) of Schedule 12 to the Northern Ireland Act 1998 (c.47) provides that references in existing legislation to a minister in charge of a particular Northern Ireland Ministry are to be construed as references to the Northern Ireland Minister in charge of that Northern Ireland Department. The Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland were renamed the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development respectively by article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1) and retained their previous functions by virtue of section 95(5) of the 1998 Act. Paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000 (c. 1) has effect during suspension of devolved government pursuant to section 1(8) of that Act: it provides that the functions of a Northern Ireland Minister who was in charge of a Northern Ireland Department immediately before the coming into force of section 1 of the Act may be discharged by that Department subject, according to paragraph 4(1)(f) of the Schedule, to the direction and control of the Secretary of State. Section 1(8) of the 2000 Act is in force by virtue of article 2 of the Northern Ireland Act (Suspension of Devolved Government) Order 2002 (S.I. 2002/2574).

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

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

(**e**) 1973 c. 51.

(**f**) 1968 c. 67. This subsection applies by virtue of section 1(3) of the Medicines Act 1971.

And after carrying out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)(**a**);

Make the following Regulations:

**Citation, commencement and scope**

**1.**—(1) These Regulations may be cited as the Medicines (Products for Animal Use—Fees) Regulations 2004 and shall come into force on 17th November 2004.

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

**Interpretation**

**2.**—(1) In these Regulations—

"the Act" means the Medicines Act 1968;

"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 32.1 of Directive 2001/82/EC 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 Article 33 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 2001/82/EC" means Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**b**);

"EEA Agreement" means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992(**c**), amended as at the date of making these Regulations**d**);

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

"export certificate" means a certificate issued under section 50 of the Act;

"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(**e**);

"product" means a medicinal product as defined in the 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;

(ii) any article or substance in relation to which provisions of Part II of the Act have effect by virtue of an order under section 104 or 105 of that Act; and

(iii) any veterinary medicinal product which would not otherwise count as a medicinal product; and

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(**a**) OJ No. L31, 1.2.2002, p. 1.
(**b**) OJ No. L311, 28.11.2001, p. 1.
(**c**) OJ No. L1, 3.1.94, p. 1.
(**d**) For latest amendments see OJ No. L130, 29.4.2004, p. 3.
(**e**) OJ No. L214, 24.8.93, p. 1.

(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 the competent authority of a Member State(**a**), as it was immediately before repeal;

"Regulation (EC) No 1084/2003" means Commission Regulation (EC) No 1084/2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State(**b**);

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

"the relevant authority" insofar as it is used in relation to a marketing authorisation or an application therefor, means the Secretary of State, and otherwise means the licensing authority as defined in section 6 of the Act;

"specific batch control" means consideration by the relevant authority of a marketing authorisation or animal test certificate holder's documentation relating to a specific batch of a veterinary medicinal product (other than an immunological product) where the quality characteristics of that product or of a material used during its manufacture or its packaging to produce the finished product for sale differ from those detailed in the marketing authorisation or animal test certificate, so that the relevant authority may decide whether action under Article 84 of Directive 2001/82/EC either to instigate a recall or to prohibit the placing on the market of the veterinary medicinal product would be required;

"variation with extras" means changes to a marketing authorisation falling within Annex II to Regulation (EC) No 541/95 except in the case of a mutually recognised marketing authorisation, where it means changes falling within Annex II to Regulation (EC) 1084/2003;

"veterinary medicinal product" has the same meaning as in Article 1.2 of Directive 2001/82/EC; and

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

(2) Expressions used in relation to variations to marketing authorisations (other than mutually recognised marketing authorisations) have the same meaning as in Directive 851/81/EC on the approximation of the laws of the Member States relating to veterinary medicinal products(**e**), as it was immediately before repeal, and Regulation (EC) No 541/95.

(3) Expressions used in relation to mutually recognised marketing authorisations have the same meaning as in Directive 2001/82/EC and Regulation (EC) No 1084/2003.

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

(5) Save as otherwise provided other expressions used in these Regulations have the same meaning as in the Act and the Medicines Act 1971.

**Applications for authorisations, licences and certificates**

**3.**—(1) Part 2 of Schedule 1 (application fees for a marketing authorisation, manufacturer's licence, product licence, wholesale dealer's licence, an animal test certificate or export certificate) shall have effect.

(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 9(2) or on an applicant for a variation with extras.

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(**a**) OJ No. L55, 1.3.95, p. 7, repealed by Regulation (EC) No. 1084/2003 (OJ No. L159, 27.6.2003, p. 1).
(**b**) OJ No. L159, 27.6.2003, p. 1.
(**c**) S.I. 1994/3142, amended by S.I. 1997/654, 1998/1048, 1999/3142, 2000/776 and 2002/269.
(**d**) S.I. 1970/1304.
(**e**) OJ No. L317, 6.11.81, p. 1, repealed by Directive 2001/82/EC.

**Specific batch control**

**4.** Where the holder of a marketing authorisation (other than a mutually recognised marketing authorisation) or an animal test certificate requests the relevant authority to undertake specific batch control he shall pay a fee of £500.

**Applications for assistance in connection with mutual recognition**

**5.** Part 3 of Schedule 1 (fees for assistance in connection with a mutual recognition application) shall have effect.

**Applications for variation of authorisations, licences and certificates**

**6.**—(1) Part 4 of Schedule 1 (fees for an application to vary a marketing authorisation, product licence, manufacturer's licence, wholesale dealer's licence or an animal test certificate) shall have effect.

(2) Paragraph (1) extends to applications for a variation with extras.

(3) Paragraph (1) shall not apply to—

(a) a variation of a marketing authorisation, licence or certificate consequential upon another variation of the same marketing authorisation, licence or certificate applied for in the same application;

(b) a variation application made at the express written invitation of the relevant authority;

(c) a TSE variation application,

for which no fee is payable.

(4) For the purposes of paragraph (3), "TSE variation application" means an application (other than a complex application as defined in Schedule 1 or an application which seeks to demonstrate compliance by cross-referring to data held by the relevant authority) to vary—

(a) a marketing authorisation to comply with regulation 6(1)(d) of the 1994 Regulations; or

(b) a product licence to reduce the risk of revocation under section 28(3) of the Act by reason of the relevant authority not being satisfied that the product was manufactured in the manner carrying the least risk of transmitting animal spongiform encephalopathy agents.

**Applications for renewal of authorisations, licences and certificates**

**7.**—(1) The fee —

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

(b) to terminate a marketing authorisation or product licence and for it to be replaced with a new marketing authorisation or product licence in respect of the same product,

is that prescribed in Part 5 of Schedule 1.

(2) 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, he shall pay the fee payable pursuant to paragraph (1) 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**

**8.**—(1) Fees for inspections in connection with an application for the grant, variation or renewal of a manufacturer's licence or for any other inspection in connection with such a licence shall be paid by the applicant or holder of the licence in accordance with Schedule 2 except as provided below.

(2) Where a manufacturing site in a non-EEA state is specified in a marketing authorisation or product licence or an application therefor and the site is inspected by the relevant authority, the

marketing authorisation or product licence holder or applicant shall pay the relevant fee prescribed in Schedule 2; and if there is more than one marketing authorisation or product licence or application therefor in which the site in question is inspected, liability to pay the relevant fee prescribed in Schedule 2 shall be divided between the holders of or applicants for those marketing authorisations or product licences, as the case may be, in proportion to the number of marketing authorisations or product licences for products manufactured at that site held or applied for by each.

(3) 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 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**

**9.**—(1) The holder of any marketing authorisation or product licence shall, following each anniversary of the grant of the authorisation or licence, provided that the product to which it relates has been sold, supplied or manufactured during the year ending on that date, pay an annual fee calculated in accordance with Schedule 3 in respect of that year.

(2) Where, during the course of the year in question, a new marketing authorisation or product licence has been granted in accordance with regulation 7(1)(b), 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**

**10.** The holder of a manufacturer's licence, other than one specified in paragraph 4(2) of Part 2 of Schedule 1, shall pay an annual fee of £230 following each anniversary of the grant of the licence.

**Wholesale dealer's licences: annual fees**

**11.**—(1) The annual fee for a wholesale dealer's licence is, where turnover is—

(a) certified to be lower than £40,000, £230; and

(b) otherwise £465.

(2) The annual fee is payable by the licence holder 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 year, and it counts as certified to be lower than £40,000 when payment of the annual fee is accompanied by a declaration of that actual lower amount.

**Registration of homoeopathic veterinary medicinal products**

**12.**—(1) Schedule 4 (fees relating to applications for registration of homoeopathic veterinary medicinal products) shall have effect.

(2) A person who applies to the Ministers to renew the registration of a product shall pay a fee of £90.

(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 £105.

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

(5) For the purposes of this regulation and Schedule 4 the terms—

"Article 8 dossier";

"the Board";

"the Ministers"

"product"; and

"registered",

shall have the meanings respectively given to them by regulation 2(1) of the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997(**a**), as read, in the case of the expression "the Ministers", with regulation 2(5) of those Regulations.

**Fees for references to the Veterinary Products Committee or to the Medicines Commission**

**13.** 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;

(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; or

(c) in relation to an application for a variation with extras insofar as it falls within regulation 9 of the 1994 Regulations,

the applicant shall pay, within 14 days following notice of the reference being sent to him, the relevant fee prescribed in Schedule 5.

**Payment of fees**

**14.**—(1) Any fee due under these Regulations is payable to the Secretary of State.

(2) Fees for an application or request shall be paid by its maker at the time it is made.

(3) Paragraph (2) does not apply to fees due under regulation 9, 10 or 11 or for any inspection, which shall be paid no later than 30 days after the date of notice requiring payment being sent by the Secretary of State to the person by whom the fee is payable.

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

(a) a lesser fee was due, the excess shall be refunded; or

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

(5) The relevant authority need not and to the extent required by Regulation (EC) 1084/2003 shall not process an application or request in connection with—

(a) a marketing authorisation, animal test certificate, export certificate or specific batch control; or

(b) a manufacturer's or wholesale dealer's licence relating to products to which Directive 2001/82/EC applies,

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

(6) In the case of any relevant variation application, the relevant authority—

(a) may by notice sent to the applicant specify the difference between the appropriate fee payable and the fee paid, explaining the reason for it and stipulating that, if the difference in question is not paid by the date 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

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

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

(7) Nothing in paragraph (6) shall be construed as preventing the relevant authority from fulfilling its obligations to observe the duties imposed on Member States under Articles 81 or 83 of Directive 2001/82/EC.

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

**Late payment of annual fees**

**15.**—(1) Where a person fails to pay the annual 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;

(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; and

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

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

(3) Where the person to whom regulation 9(1) applies has not furnished evidence of his annual turnover in accordance with the provisions of paragraph 2 of Schedule 3 so that the annual fee cannot be determined before the due date, he may make a payment of an amount on account of the annual fee.

(4) Where paragraph (3) applies and a payment on account has been made, any additional fee payable under this regulation shall be calculated as if, in paragraph (1) above, the reference to the annual fee 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, "the due date" means the date of the written notice sent in accordance with regulation 14(3).

**Suspension of licences and certificates**

**16.**—(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 requiring payment 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 sum remains unpaid, the relevant authority may forthwith suspend the licence or certificate until the sum has been paid.

(2) In paragraph (1), "licence" does not include a manufacturer's or wholesale dealer's licence for products to which Directive 2001/82/EC applies.

**Waiver, reduction or refund of fees**

**17.**—(1) The relevant authority—

(a) may waive or reduce payment of any fee payable under these Regulations or refund the whole or part of any fee already so paid—

(i) on an individual application to do so, if it concludes that exceptional circumstances justify it;

(ii) in any of the circumstances specified in paragraphs 1 to 3 of Schedule 6; and

(b) shall do so as required by paragraph 4 of Schedule 6.

(2) Paragraph (1)(a)(ii) does not apply to products covered by regulation 12.

**Revocation**

**18.** The following Regulations are hereby revoked:

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

(b) The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 1999(**b**);

(c) The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000(**c**);

(d) The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2001(**d**);

(e) The Medicines (Products for Animal Use—Fees) (Amendment) (No. 2) Regulations 2001(**e**);

(f) The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2002(**f**); and

(g) The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2003(**g**).

**Transitional provisions**

**19.**—(1) These Regulations shall not apply in respect of any application made before the date these Regulations come into force.

(2) Paragraph (1) does not apply where an—

(a) inspection is made after the date these Regulations come into force in connection with an application made before that date, in which case the inspection fee payable is that due under these Regulations; or

(b) application to renew a marketing authorisation, licence or certificate due to expire after these Regulations come into force is made before that date, in which case the fee payable is that due under these Regulations.

*Ben Bradshaw*

Parliamentary Under Secretary of State,
Department for Environment, Food and Rural Affairs

15th October 2004

L.S.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

*D C Gowdy*
Permanent Secretary,
Department of Health, Social Services and Public Safety

14th October 2004

L.S.

Sealed with the Official Seal of the Department of Agriculture and Rural Development

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(**a**) S.I. 1998/2428.
(**b**) S.I. 1999/2512.
(**c**) S.I. 2000/2250.
(**d**) S.I. 2001/1669.
(**e**) S.I. 2001/3751.
(**f**) S.I. 2002/2569.
(**g**) S.I. 2003/2957.

*Gerald Lavery*
Deputy Secretary,
15th October 2004 Department of Agriculture and Rural Development

We consent.

*Nick Ainger*
*Joan Ryan*

21st October 2004 Two of the Lords Commissioners of Her Majesty's Treasury

# SCHEDULE 1 Regulations 2, 3, 5, 6, 7 and 10

## 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 1

### Interpretation

In this Schedule—

"abridged standard", in relation to an application, describes 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 13.1 of Directive 2001/82/EC 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;

"Animal Test Certificate—Type A application" means an application for a certificate in relation to a medicinal test on animals under section 32 of the Act with respect to—

(c) an immunological veterinary medicinal product which has been authorised in a Member State for use with species on whom the proposed test will be conducted;

(d) a pharmaceutical veterinary medicinal product which has been authorised in a Member State for use with food-producing species on which the proposed test will be conducted where the same or a similar dosage regime and method of administration is to be used in the medicinal test as is authorised; or

(e) a pharmaceutical medicinal product authorised in a Member State for human or animal use where the test is to be conducted on companion animals only;

"Animal Test Certificate—Type B application" means an application for a certificate under section 32 of the Act which does not fall within the definition for "Animal Test Certificate—Type A application";

"Article 26.3 marketing authorisation" means an authorisation of the type provided for in Article 26.3 of Directive 2001/82/EC;

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

"Category I", in relation to an application, describes an application for assistance in connection with a mutual recognition application other than a Category II or III application;

"Category II", in relation to an application, describes 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", in relation to an application, describes 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", in relation to an application, describes 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 containing the same active ingredient as the product in question has not previously been granted in the United Kingdom;

(i) relates to a container directly in contact with a sterile product, that container being made from a material different from that used for the container of any sterile product—

(i) which contains the same active ingredient as the sterile 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 and in circumstances in which no suitable authorised or licensed vaccines are readily available and, in relation to an application, describes an application limited to use of an emergency vaccine, for a product licence;

"excipient", in relation to an immunological veterinary medicinal product, includes an adjuvant;

"immunological veterinary medicinal product" has the same meaning as in Directive 2001/82/EC;

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

(a) a mutually recognised marketing authorisation, a change covered by any single numbered paragraph of Annex I to Regulation (EC) No 1084/2003;

(b) any other authorisation or licence or certificate, a change to 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 relevant authority in respect of a veterinary medicinal product which—

(a) is imported into the United Kingdom from an EEA State;

(b) has been granted a marketing authorisation by an EEA State; and

(c) has no therapeutic effect different from that of a veterinary medicinal product already granted a marketing authorisation in the United Kingdom;

"major", in relation to an application, describes 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;

"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;

(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 a lawful 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 3.4 of Regulation (EC) No 1084/2003;

"simple", in relation to an application, describes 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 is the same;

(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", in relation to an application, describes an application which is not a major, complex, abridged standard or simple application;

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

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

"Type IA notification" means a variation of a mutually recognised marketing authorisation of a type listed in the Table in Annex I to Regulation (EC) No 1084/2003 in respect of which the note "IA" is entered in the final column of that Table;

"Type IB", in relation to a variation, describes a variation of a mutually recognised marketing authorisation of a type listed in the Table in Annex I to Regulation (EC) No 1084/2003 in respect of which the note "IB" is entered in the final column of that Table; and

"Type II", in relation to a variation, describes a variation of a mutually recognised marketing authorisation of the type referred to in Article 3.3 of Regulation (EC) No 1084/2003.

# PART 2

## Fees Relating to Applications for the Grant of Marketing Authorisations, Product Licences, Manufacturer's Licences, Wholesale Dealer's Licences, Animal Test Certificates and Export Certificates

*Marketing authorisations and product licences*

**1.** The fee for an application is that specified in the table below.

| *Type of application* | *type A marketing authorisation(£)* | *type B marketing authorisation (£)* | *product licence (£)* | *Article 26.3 marketing authorisation (£)* |
|---|---|---|---|---|
| Major | 22,270 | 12,285 | 22,270 | 12,920 |
| Complex | 12,920 | 7,375 | 12,920 | 5,580 |
| Standard | 5,580 | 3,690 | 5,580 | — |
| Abridged standard | 4,360 | — | — | — |
| Simple | 1,555 | 975 | 1,555 | — |
| Emergency vaccine | — | — | 40 | — |

**2.** Paragraph 1 shall not apply where an application for a marketing authorisation is made by a person who is already the holder of an Article 26.3 marketing authorisation relating to the same veterinary medicinal product as the marketing authorisation applied for, in which case the fee shall be—

(a) where a major application was previously made in respect of the Article 26.3 marketing authorisation, £9,350;

(b) where a complex application was previously made in respect of the Article 26.3 marketing authorisation, £7,340.

**3.**—(1) This paragraph applies to fees which would, but for this paragraph, be payable by reference to paragraph 1, whether or not as qualified by paragraph 2.

(2) Where a major or a complex application is made by a person who is already the holder of—

(a) an animal test certificate, in respect of a product containing the same active ingredient;

(b) a marketing authorisation or product licence covering export only, relating to the same product,

the fee shall be reduced by the amount of the application fee paid for that certificate or licence.

(3) Where an applicant has made an original request (that is to say a set of one or more applications where each product contains the same active ingredient or the same combination of active ingredients) 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 payable 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, but there shall be allowed against it the net total of any fees paid in respect of the original request.

(4) Where an applicant has pending one or more major applications for a marketing authorisation or product licence and each product contains the same active ingredient or combination of active ingredients the fees payable shall be the fee for a major application under paragraph 1 in respect of the first application and for each additional application—

(a) which relates to a product of a different dosage form, the fee for a complex application under paragraph 1;

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

(5) Where an applicant has pending one or more complex applications for a marketing authorisation or product licence and each product contains the same active ingredient or combination of active ingredients the fees payable shall be the fee for a complex application under paragraph 1 in respect of the first application and for each additional application—

(a) which relates to a product of a different dosage form, the fee for a standard application under paragraph 1;

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

*Manufacturer's licences*

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

(a) in a case to which sub-paragraph (2) below applies, £110; or

(b) in any other case £2,505; 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 sub-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 would require a product licence but for article 2(2)(i) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(**a**); or

(b) emergency vaccines.

*Wholesale dealer's licences*

**5.**—(1) The fee for an application for a wholesale dealer's licence is £1,455.

(2) Paragraph (1) does not apply where turnover in the first year of trading is less than £40,000 in which case the fee is £595 provided that payment is accompanied by an estimate of that year's turnover.

(3) Following the first anniversary of the grant of a wholesale dealer's licence, where a fee of £595 was paid, the holder shall, together with his payment of the next annual fee payable under regulation 11(1), send a declaration certifying his turnover for his first year of trading.

(4) If either a declaration, as required by sub-paragraph (3) above, is not sent or the declaration shows that turnover for the first calendar year of trading was £40,000 or more, the wholesale dealer shall pay the balance of £860 no later than 30 days after the first anniversary of the grant of the licence.

(5) Where a wholesale dealer has paid the full fee but his turnover for the first year of trading was lower than £40,000, if he sends a declaration certifying the actual lower turnover, the relevant authority shall refund the excess.

(6) For the purposes of this paragraph, "turnover" has the same meaning as in regulation 11 and "trading" means trading as a wholesale dealer.

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(**a**) S.I. 1971/1450.

*Animal test certificates*

**6.** The fee for an Animal Test Certificate—Type A application is £305, and the fee for an Animal Test Certificate—Type B application is £735.

*Marketing authorisations (parallel import)*

**7.** The fee for an application for a marketing authorisation (parallel import) is £1,745.

*Export Certificates*

**8.** The fee for an application for an export certificate is £25 and, for the supply of a certified copy of the original certificate, £10.

# PART 3

## Fees Relating to Applications for Assistance in Connection with Mutual Recognition Applications

**1.**—(1) The fee for an application for assistance in connection with a mutual recognition application made no more than six months after the grant of the marketing authorisation to which it relates is as specified in the second column of the table below.

(2) Where subsequent applications of the type described in sub-paragraph (1) are made no more than six months of the grant of the marketing authorisation the fee payable shall be that specified in the third column of the table for the sixth and each additional Member State which was not covered by the previous applications.

| *Type of application* | *Basic Fee (£)* | *Additional Fee for the sixth and each additional Member State (£)* |
|---|---|---|
| Major | 3,995 | 865 |
| Complex | 2,670 | 420 |
| Standard | 1,150 | 215 |
| Simple | 390 | 70 |

**2.**—(1) The fee for an application for assistance in connection with a mutual recognition application made more than six months after the grant of the marketing authorisation to which it relates is as specified in the second column of the table below.

(2) Where subsequent applications of the type described in sub-paragraph (1) are made within six months of that application for assistance the fee payable shall be that specified in the third column of the table for the sixth and each additional Member State which was not covered by the previous applications.

| *Type of application* | *Basic Fee (£)* | *Additional Fee for the sixth and each additional Member State (£)* |
|---|---|---|
| Category I | 9,795 | 1,230 |
| Category II | 6,540 | 820 |
| Category III | 5,230 | 655 |

# PART 4

## Fees Relating to Applications for the variation of Marketing Authorisations, Product Licences, Manufacturer's Licences, Wholesale Dealer's Licences and Animal Test Certificates

**1.** The application fee for a variation to a marketing authorisation of a type specified in the table below is that specified opposite it.

| | *Type of variation* | *Fee (£)* |
|---|---|---|
| 1 | Change following modification(s) to the manufacturing authorisation | 620 |
| 2 | Change in the name of the medicinal product (either invented name or common name) | 620 |
| 3 | Change in the name and/or address of the marketing authorisation holder | 240 |
| 4 | Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients) | 620 |
| 5 | Change in the colouring system of the product (addition, deletion or replacement of colourant(s)) | 620 |
| 6 | Change in the flavouring system of the product (addition, deletion or replacement of flavour(s)) | 620 |
| 7 | Change in coating weight of tablets or change in weight of capsule shells | 620 |
| 8 | Change in the qualitative composition of immediate packaging material | 620 |
| 9 | Deletion of an indication | 620 |
| 10 | Deletion of a route of administration | 620 |
| 11 | Addition or replacement of measuring device for dosage forms | 620 |
| 12 | Change in the manufacturer(s) of active substance | 620 |
| 13 | Change in name of manufacturer of active substance | 240 |
| 14 | Change in supplier of intermediate compound used in the manufacture of the active substance | 620 |
| 15 | Minor change of manufacturing process of the active substance | 620 |
| 16 | Change in specification of starting material or intermediate used in the manufacture of the active substance | 620 |

| | | |
|---|---|---|
| 17 | Change in batch size of active substance | 620 |
| 18 | Change in specification of active substance | 620 |
| 19 | Minor change in manufacture of the medicinal product | 620 |
| 20 | Change in in-process controls applied during the manufacture of the product | 620 |
| 21 | Change in the batch size of finished product | 620 |
| 22 | Change in specification of the medicinal product | 620 |
| 23 | Synthesis or recovery of non-pharmacopoeial excipients which had been described in the original dossier | 620 |
| 24 | Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines) | 620 |
| 25 | Extension of shelf life as foreseen at time of authorisation | 620 |
| 26 | Extension of the shelf life or retest period of the active substance | 620 |
| 27 | Change in shelf life after first opening | 620 |
| 28 | Change in shelf life after reconstitution | 620 |
| 29 | Change in the storage conditions | 620 |
| 30 | Change in test procedure of active substance | 620 |
| 31 | Change in test procedure for a starting material or intermediate used in the manufacture of the active substance | 620 |
| 32 | Change in the test procedures of the medicinal product | 620 |
| 33 | Changes to comply with supplements to pharmacopoeias | 620 |
| 34 | Change in test procedures of non-pharmacopoeial excipients | 620 |
| 35 | Change in test procedure of immediate packaging | 620 |
| 36 | Change in test procedure of administrative device | 620 |
| 37 | Change in pack size for a medicinal product | 620 |
| 38 | Change in container shape | 620 |
| 39 | Change of imprints, bossing or other markings (except scoring) on tablets or printing on capsules, including addition or changes of inks used for product marking | 620 |
| 40 | Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitive composition and mean mass | 620 |
| 41 | Change in the manufacturing process of a non proteinaceous component due to the subsequent introduction of a biotechnology step | 620 |

**2.** The application fee for any other variation to a marketing authorisation (other than a mutually recognised marketing authorisation), or for any variation to a product licence, shall be £2,460 save as provided in the table below.

| | *Type of variation* | *Fee (£)* |
|---|---|---|
| 1 | Change made simultaneously as a change made to another product by the same marketing authorisation holder where the changes are identical and there is identical supporting data | 240 |
| 2 | Change of distributor where no other aspects of the dossier are changed and the marketing authorisation holder remains the same | 240 |
| 3 | Change of marketing authorisation holder where no other aspects of the dossier are changed | 240 |
| 4 | Simple dosage instruction changes where the change is not the result of safety concerns, no new studies are required to support the change and the dose in mg/kg body weight remains the same | 620 |
| 5 | Addition or change to user safety warnings where no other aspects of the dossier are changed, no user safety warnings are removed, no new studies are required to support the change and the proposed warnings serve to increase the protection of the user | 620 |
| 6 | Corrections or simple text layout changes to summary of product characteristics and/or product literature where the changes are not a result of safety concerns, no new studies are required to support the change and no other aspects of the dossier are changed | 620 |
| 7 | Any change to a licence relating solely to an emergency vaccine | 40 |

*Mutually recognised marketing authorisations*

**3.**—(1) The fee for an application for the variation of a mutually recognised marketing authorisation shall, in respect of each individual variation to which the application relates, be that specified in the table below.

(2) In the table, "connected variation" means a variation to which sub-paragraph (1) applies made simultaneously or after a variation application for another such authorisation for which a fee is paid in pursuance of sub-paragraph (1), and where, for both applications the data relied upon and the applicant is the same.

| *Mutually recognised marketing authorisation variation type* | *Fee—United Kingdom acting as the Reference Member State (£)* | *Fee—United Kingdom not acting as the Reference Member State (£)* |
|---|---|---|
| Type IA notification | 1,590 | 240 |
| Type IB | 2,615 | 240 |
| Type II | 9,145 | 2,460 |
| Variation with extras | 10,460 | 4,375 |
| Connected variation | 1,590 | 240 |

*Manufacturer's licences*

**4.** The fee for an application for the variation of a manufacturer's licence is £150 for each individual variation save that the fee is—

(a) £110 in respect of a licence to which paragraph 4(2) of Part 2 of this Schedule applies;

(b) £445 where scientific or pharmaceutical assessment is required.

*Wholesale dealer's licences*

**5.** The fee for an application for a variation of a wholesale dealer's licence is £150 for each individual variation save that the fee is £445 where scientific or pharmaceutical assessment is required.

*Animal test certificates*

**6.** The fee for an application for the variation of an animal test certificate is £240 in respect of each individual variation.

# PART 5

## 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.** The fee for an application to renew a marketing authorisation or product licence or the grant of such an authorisation or licence in circumstances to which regulation 7(1)(b) applies—

(a) for an emergency vaccine is £40;

(b) for a herbal product is £375; and

(c) in any other case is £1,110.

*Manufacturer's licences*

**2.** The fee for an application to renew a manufacturer's licence only relating to products to which paragraph 4(2) of Part 2 of this Schedule applies is £110.

*Animal test certificates*

**3.** The fee for an application to renew an animal test certificate is £115.

*Article 26.3 marketing authorisations*

**4.** Where an Article 26.3 marketing authorisation is renewed, paragraph 1 does not apply in respect of the first renewal application, in which case no fee is payable.

# SCHEDULE 2

Regulation 8

## Fees relating to site inspections

*Interpretation*

**1.**—(1) In this Schedule—

"biological product" has the same meaning as set out in Part 1 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 Directive 2001/82/EC;

"major", in relation to an inspection, describes an inspection at a site at which 60 or more, but fewer than 250, relevant persons are employed;

"minor", in relation to an inspection, describes an inspection at a site at which fewer than 10 relevant persons are employed;

"relevant person" means any person directly or indirectly engaged, or assisting in the activity of manufacturing or assembling products and includes any person whose work involves management, quality control, site maintenance, packing, storage or distribution;

"standard", in relation to an inspection, describes an inspection at a site at which 10 or more, but fewer than 60, relevant persons are employed; and

"supersite", in relation to an inspection, describes 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 relevant work) shall be included in the calculation *pro rata*.

*Fees*

**2.**—(1) The fee for an inspection is that specified in the table below.

| *Type of inspection* | *Fee (£)* |
|---|---|
| Supersite | 10,300 |
| Major | 5,420 |
| Standard | 3,885 |
| Minor | 2,095 |

(2) Sub-paragraph (1) does not apply 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 in which case the fee payable is that specified in the table below.

| *Type of inspection* | *Fee (£)* |
|---|---|
| Supersite | 17,085 |
| Major | 9,440 |
| Standard, covering immunological veterinary medicinal products | 6,160 |
| Other standard | 4,640 |
| Minor, covering immunological veterinary medicinal products | 3,105 |
| Other minor | 3,105 |

(3) Sub-paragraph (1) does not apply where the site inspected is concerned only with the assembly of products, in which case the fee payable is that specified in the table below.

| *Type of inspection* | *Fee (£)* |
|---|---|
| Supersite | 7,485 |
| Major | 5,055 |
| Standard | 2,480 |
| Minor | 1,280 |

(4) Sub-paragraph (1) does not apply where the site inspected is limited solely to the manufacture or assembly of—

(a) products the sale or supply of which would require a product licence but for article 2(2)(i) of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971, in which case the fee payable is £105;

(b) emergency vaccines, in which case the fee payable is £115;

(c) products covered by paragraph (a) above and vaccines covered by paragraph (b), in which case the fee payable is £200.

**3.** Paragraph 2 does not apply to a biological product (not being a dormant biological product), for which—

(a) a marketing authorisation or product licence was granted because it was identical to an existing product, in which case the inspection fee is £65;

(b) the fee for any inspection limited to either or both of the premises where it is manufactured or assembled and the procedures for its quality control is £1,480.

**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 and any additional costs reasonably incurred by them on account of it being outside the United Kingdom.

(2) For the purposes of sub-paragraph (1), the fees of an interpreter shall be regarded as an additional cost capable of being reasonably incurred.

# SCHEDULE 3

Regulation 9

## Marketing authorisations and product licences: annual fees

*Calculation of turnover*

**1.** 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;

"manufacturers' prices" means the prices charged for authorised or licensed products by manufacturers to wholesalers, except to the extent that—

(a) the products are supplied by manufacturers direct to retailers, in which case it means 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;

(b) a marketing authorisation or product licence holder sells or supplies products which he has neither manufactured nor obtained from the manufacturer, in which case it means the prices paid by him for those products.

**2.**—(1) The relevant authority may require a marketing authorisation or product licence holder to furnish an auditor's certificate evidencing his turnover.

(2) If within one month of the date by which such certificate is required, or such longer period as the relevant authority may allow, the marketing authorisation or product licence holder has failed to furnish it, the annual fee payable shall be calculated as provided for in paragraph 4 or may 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.

*Calculation of annual fees*

**3.**—(1) The annual fee shall be—

(a) in the case of emergency vaccines, 0.71% of turnover, rounded up to the nearest £1, except that the minimum sum payable shall be £10; and

(b) in all other cases either 0.61% of turnover or £205 whichever is the greater, plus for each marketing authorisation or product licence held, where turnover is—

(i) below £208,000, £26;

(ii) £208,000 or more, £208.

(2) Where application of sub-paragraph (1)(b) incorporates an amount charged on a percentage basis the annual fee shall be rounded up to the nearest £10.

**4.** Where this paragraph applies, the annual fee payable by the marketing authorisation or product licence holder shall be £10,000 together with an additional £2,000 for each product in respect of which a marketing authorisation or product licence is held.

**5.** Where an annual fee calculated in accordance with paragraph 4 has been paid and the relevant authority is subsequently satisfied as to the turnover for the relevant calendar year, the difference between the amount paid and the annual fee calculated in accordance with paragraph 3 (if less) may be refunded by the relevant authority.

**6.** Any sums payable to a person by way of refund under paragraph 5 may be treated as having been paid on account of any other fee which that person is liable to pay under these Regulations.

# SCHEDULE 4

Regulation 12

## Fees relating to applications for registration of homoeopathic veterinary medicinal products

*Interpretation*

**1.** In this Schedule—

"formulation", in relation to a product, does not include the formulation of a homoeopathic stock contained in the product;

"homoeopathic stock" has the same meaning as in article 1.8 of Directive 2001/82/EC.

"identical" means in relation to—

(a) the formulation of a product, identical as regards its qualitative composition, preparation and testing;

(b) a homoeopathic stock, identical as regards its source, composition, preparation and testing;

"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 markets; or

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

(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 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 —

(a) registered product—

(i) which the applicant markets; or

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

(b) product in respect of which the applicant has made a simultaneous application; and

"simultaneous application" means the first of applications submitted at the same time by the same applicant to be considered by relevant authority.

*Fees relating to applications for registration*

**2.** The fee for a registration application is that specified in the table below.

| *Type of application* | *Fee—product prepared from not more than 5 homoeopathic stocks (£)* | *Fee—product prepared from more than 5 homoeopathic stocks (£)* |
|---|---|---|
| For a product prepared solely from a repeat stock or stocks and of repeat formulation | 130 | 305 |
| For a product which is either<br>(a) prepared solely from a repeat stock or stocks; or<br>(b) of repeat formulation | 375 | 545 |
| Any other application | 620 | 800 |

*Waiver or refund of fees*

**3.**—(1) Where an application for registration is withdrawn before determination by the relevant authority, 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 no assessment (veterinary, scientific or pharmaceutical) has begun, 90%;

(b) if such 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 Veterinary Products Committee or by the Medicines Commission, no refund or waiver of the fee payable in connection with that application shall be made.

# SCHEDULE 5

Regulation 13

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

**1.** The fee for a reference to the Veterinary Products Committee or to the Medicines Commission in connection with an application for—

(a) a marketing authorisation or licence is that specified in the table below;

(b) an animal test certificate is £610; and

(c) a variation with extras to which regulation 13(c) applies is £960.

| *Type of application* | *Fee (£)* |
|---|---|
| Major | 1,755 |
| Complex | 1,010 |
| Standard | 465 |
| Simple | 180 |

**2.** For the purposes of this Schedule, the terms—

"complex";

"major";

"simple"; and

"standard",

have the meanings given to them in Part 1 of Schedule 1.

## SCHEDULE 6

Regulation 17

## 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 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 such products; or

(b) in respect of any inspection made during the currency of such a marketing authorisation or product licence,

shall be waived during that period or, if the period will or is likely to exceed 3 months, during the first 3 months.

**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 varied or an inspection to be made; and

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

(i) is not intended for sale; or

(ii) is intended only for use in the treatment of rare conditions or in the treatment of a minor species of animal or as an emergency vaccine.

**3.**—(1) 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 payable under these Regulations for a marketing authorisation or product licence application or for a variation or first application for a renewal thereof or for an inspection in relation to the product during the currency of that authorisation or licence, made during that five year period application may be reduced or, if the fee has already been paid, 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 estimated by the relevant authority and the sum of £40,000.

(2) Before a marketing authorisation or product licence holder or applicant pays any reduced fee or receives any refund pursuant to sub-paragraph (1) he shall furnish evidence to the satisfaction of the relevant authority of the actual or estimated amount of annual turnover of the product for 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) at the time of the application on the basis of the estimated maximum turnover of the product during any of the first five years of the currency of the authorisation or product licence, that fee shall be regarded as a provisional payment on account.

(4) Where a provisional payment on account was made and evidence furnished to the relevant authority's satisfaction pursuant to sub-paragraph (2) shows that the maximum turnover in any of those years—

(a) exceeded £40,000, the 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 14(3);

(b) was less than the estimated maximum turnover, the relevant authority may refund the balance between the amount so paid and that payable calculated in accordance with sub-paragraph (1).

**4.**—(1) 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 in connection with that application:

(a) if no assessment (veterinary, scientific or pharmaceutical) has begun, 90%;

(b) if such assessment has begun but not been completed, 50%, except where paragraph (c) applies;

(c) if such assessment has begun but not been completed and 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 23 of Directive 2001/82/EC as applied by regulation 5 of the 1994 Regulations, 25%.

(2) In the case where an application has been withdrawn under sub-paragraph (1)(b), and a 50% refund of the fee has been made, any re-application in respect of the same product by the same applicant shall be charged at 50% of the fee otherwise payable under these Regulations.

(3) 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 shall be made under this paragraph.

## EXPLANATORY NOTE

*(This note is not part of the Order)*

These Regulations revoke and re-enact with modifications the Medicines (Products for Animal Use—Fees) Regulations 1998 ('the 1998 Regulations') (S.I. 1998/2428), together with the instruments which amend them. As in the case of the 1998 Regulations, they prescribe fees in connection with applications and inspections relating to—

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

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

(c) the registration of homoeopathic veterinary medicinal products under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997 (S.I. 1997/322).

References to EC legislation have, where appropriate, been updated.

The only change to the fee structure in these Regulations is that in relation to annual fees for marketing authorisations and product licences, the differentiation between veterinary medicinal products with a turnover of under or over £2.8m is abolished. In addition there is an overall increase in fees of 8.7%,

The Regulations also provide for:

(a) the method and time for payment of fees (regulations 14 and 15);

(b) the suspension of licences and certificates where fees remain unpaid (regulation 16); and

(c) the waiver, reduction or refund of fees (regulation 17).

Regulation 19 (transitional provisions) provides that the Regulations (save for the exception in paragraph (2) of that regulation) only apply to applications made after the Regulations come into force.

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.

STATUTORY INSTRUMENTS

# 2004 No.2750

# MEDICINES

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