2003 No. 2957

MEDICINES

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

Made - - - - -	*17th November 2003*
Laid before Parliament	*19th November 2003*
Coming into force - -	*18th December 2003*

The Secretary of State for Environment, Food and Rural Affairs, 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 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 for Environment, Food and Rural Affairs, being designated(**c**) for the purposes of section 2(2) of the European Communities Act 1972(**d**) in relation to medicinal products and the Common Agricultural Policy of the European Community, in exercise of the powers conferred on her by that section;

After carrying out any 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;(**e**)

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)(**f**);

(**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 1971 Act 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. Currently, these are—

(i) the Secretary of State (by virtue of article 2(2) of, and paragraph 1 of the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142), and additionally in respect of Wales, the earlier Transfer of Functions (Wales) (No. 1) Order (S.I. 1978/272); and of article 3(1)(c) and (7) of and paragraph 15 of Schedule 1 to the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002 (S.I. 2002/794)); and

(ii) the Northern Ireland Departments of Health, Social Services and Public Safety and of Agriculture and Rural Development. *See* paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000 (c. 1), which has effect during suspension: this paragraph 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. Prior to the most recent occasion of the coming into force of section 1 of the Northern Ireland Act 2000 (as a consequence of the Northern Ireland Act (Suspension of Devolved Government) Order 2002 (S.I. 2002/2574)), the Ministers of these two Northern Ireland Departments exercised the relevant functions by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283(N.I. 1).

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

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

(**e**) 1968 c. 67.

(**f**) OJ No. L31, 1.2.2002, p. 1.

Make the following Regulations:

Title, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2003, and shall come into force on 18th December 2003.

(2) In these Regulations, "the principal Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1998(**a**).

Amendment of regulations 2, 3, 12 to 17 and 19 of the Medicines (Products for Animal Use—Fees) Regulations 1998

2.—(1) Regulations 2, 3, 12 to 17 and 19 of the principal Regulations shall be amended as specified in this regulation.

(2) In regulation 2 (Interpretation)—

(a) paragraph (1) shall be amended in accordance with Schedule 1 to these Regulations.

(b) for paragraph (2) substitute:

"(2) Other expressions used in these Regulations have the same meaning as in the Act and the 1971 Act, and, in the case of variations to marketing authorisations other than mutually recognised marketing authorisations, as in Directive 851/81/EEC(**b**) and Regulation (EC) No 541/95,(**c**) but in all other cases, as in Directive 2001/82/EC(**d**) and Regulation (EC) No 1084/2003(**e**).".

(3) For regulation 3, substitute:

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

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

(2) Where a person requests from the licensing authority a certified copy of an export certificate which he has been or is to be granted, he shall pay the fee prescribed in Part II of Schedule 1, paragraph 10.

(3) 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.

Specific batch control

3A. Where the holder of a marketing authorisation (other than a mutually recognised marketing authorisation) or of an animal test certificate requests the licensing authority to undertake specific batch control in respect of a batch of a veterinary medicinal product, he shall pay a fee of £475."

(4) In regulation 12 (manufacturer's licences: annual fees), for "an annual fee of £215", substitute "an annual fee of £220".

(5) In regulation 13 (wholesale dealer's licences: annual fees),

(a) in paragraph (1), for "£430", substitute "£445"; and

(b) in paragraph (2), for "£215", substitute "£220".

(6) In regulation 14 (registration of homoeopathic veterinary medicinal products),

(a) in paragraph (2), for "£80", substitute "£85"; and

(b) in paragraph (3), for "£95", substitute "£100".

(**a**) S.I. 1998/2428 as amended by S.I. 2000/2250, S.I. 2001/1669 and 3751, and S.I. 2002/2569.
(**b**) OJ No. L317, 6.11.1981, p. 1.
(**c**) OJ No. L55, 11.3.1995, p. 7.
(**d**) OJ No. L311, 28.11.2001, p. 1.
(**e**) OJ No. L159, 27.6.2003, p. 1.

(7) In regulation 15 (marketing authorisations, product licences and animal test certificates: fees for references to the Veterinary Products Committee or to the Medicines Commission),

(a) in paragraph (a), after "renewal of an animal test certificate", delete "or" ,

(b) in paragraph (b) after "renewal of a marketing authorisation,", insert "or", and

(c) insert a new paragraph as follows:

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

(8) Regulation 16 (payment of fees) shall be amended as follows:

(a) in paragraph (1) for "the Minister of Agriculture, Fisheries and Food", substitute "the Secretary of State for Environment, Food and Rural Affairs";

(b) in paragraph (2) delete "or the Minister of Agriculture, Fisheries and Food as may be indicated on the written notice requiring payment referred to in regulation 17(2)".

(9) In regulation 17 (time for payment of fees)—

(a) in paragraph (4)—

(i) for "Regulation (EC) No 541/95," substitute " Regulation (EC) 1084/2003";

(ii) for "a marketing authorisation, or" substitute "a marketing authorisation, animal test certificate, export certificate or request for a certified copy of an export certificate, or"; and

(iii) for "Directive 81/851/EEC" substitute "Directive 2001/82/EC".

(b) after paragraph (5), insert:

"(5A) the licensing authority need not undertake specific batch control if the person who requests it has not paid or caused to be paid the fee required under these Regulations.

(5B) Nothing in paragraph (5A) shall be construed as preventing the licensing authority from fulfilling its obligations to observe the duties imposed on member States under Articles 81 or 83 of Directive 2001/82/EC.".

(10) In regulation 19(2), for "Directive 81/851/EEC" substitute "Directive 2001/82/EC".

Amendment of the Schedules to the Medicines (Products for Animal Use—Fees) Regulations 1998

3.—(1) The Schedules to the principal Regulations shall be amended as specified in this regulation.

(2) In Schedule 1—

(a) Part I (interpretation of Schedule 1) shall be amended in accordance with Schedule 2 to these Regulations;

(b) 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) shall be amended—

(i) in its heading by substituting for "and Animal Test Certificates" the phrase "Animal Test Certificates and Export Certificates";

(ii) in paragraphs 2 and 3, by substituting for the phrase "Article 15.2 marketing authorisation" wherever it appears, the phrase "Article 26.3 marketing authorisation";

(iii) by substituting the following for the text in paragraph (8) (animal test certificates):

"The fee for an Animal Test Certificate—Type A application is £290, and the fee for an Animal Test Certificate—Type B application is £700." and

(iv) after paragraph 9 by adding the following new paragraph:

"**Export Certificates**

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

(c) Part IV shall be amended—

(i) in paragraph 3 (mutually recognised marketing authorisations), Table F, by substituting for Column (1) of that Table, Column (1) of the Table set out in Schedule 3 to these Regulations, and by substituting for the fees set out in Table F, the new fees set out in Columns (2) and (3) of the Table set out in Schedule 3 to these Regulations;

(ii) by substituting for paragraph 4 the following:

"**4.**—(1) The fee for an application for a connected variation shall, in respect of each connected variation to which the application relates, be £1,515 per individual variation where the United Kingdom is acting as the Reference Member State and £230 per individual variation where the United Kingdom is not acting as Reference Member State.

(2) In this paragraph a connected variation means a variation of a kind described in an entry in column (1) of Table F of a mutually recognised marketing authorisation which is connected to a proposed variation of another such authorisation for which a fee is paid in pursuance of paragraph 3, and where—

(a) the same data is relied on for both the connected variation and the proposed variation, and

(b) the same applicant applies for the connected variation and the proposed variation."

(d) for Part V, paragraph 4 (Article 15.2 marketing authorisations) substitute the following—

"**Article 26.3 marketing authorisations**

4. Where an Article 26.3 marketing authorisation is renewed, no fee is payable in respect of the first such renewal.".

(3) In Schedule 3 in Part II (Calculation of Annual Fees), in paragraph 1, for "£280", substitute "£290".

(4) In Schedule 5 (Fees Relating to Applications for Registration of Homoeopathic Veterinary Medicinal Products)—

(a) in Part I (Interpretation)—

(i) delete the definition "the Homoeopathics Directive";

(ii) in the definition "homoeopathic stock", for "the Homoeopathics Directive" substitute "Article 1.8 of Directive 2001/82/EC;" and

(b) in Part II (Fees Relating to Applications for Registration), paragraph 2(b), for "Article 6 of the Homoeopathics Directive" substitute "Article 16 of Directive 2001/82/EC".

(5) In Schedule 6 ("Marketing Authorisations, Product Licences and Animal Test Certificates: Fees for references to the Veterinary Products Committee or to the Medicines Commission"), after paragraph 2, add the following new paragraph—

"2A. The fee payable under regulation 15(c) for a reference to the Veterinary Products Committee in connection with an application for a variation with extras insofar as it falls within regulation 9 of the 1994 Regulations shall be £960.".

(6) In Schedule 7, paragraph 4(1)(c) for "Article 9 of Directive 81/851/EEC" substitute "Article 23 of Directive 2001/82/EC".

(7) The provisions of the principal Regulations as to fees which are set out in column (1) of Schedule 4 to these Regulations shall be amended by substituting for the corresponding old fee, set out in column (3), the new fee set out alongside it in column (4) of that Schedule.

Transitional arrangements

4.—(1) Subject to paragraphs (2), (3) and (4), these Regulations shall not apply in respect of any application made before these Regulations come into force or in respect of annual fees based on turnover in a past calendar year.

(2) The fee for any inspection made after these Regulations come into force in connection with any application made before they come into force is the fee specified in these Regulations.

(3) The fee for the renewal of a marketing authorisation, licence or certificate is the fee payable at the time the renewal is due.

(4) These regulations apply in respect of annual fees which are calculated on turnover in the calendar year 2002 and which remain payable.

Ben Bradshaw
Parliamentary Under Secretary,
14th November 2003 Department for Environment, Food and Rural Affairs

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

D. Kenny
A Senior Officer of the Department of Health, Social Services and Public Safety

12th November 2003

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

Pat Toal
Permanent Secretary, Department of Agriculture and Rural Development

11th November 2003

We consent

Nick Ainger
Joan Ryan
17th November 2003 Two of the Lords Commissioners of Her Majesty's Treasury

SCHEDULE 1

Regulation 2(2)(a)

Amendments to regulation 2(1) of the principal Regulations

	Text	*Amendment*
1.	In the definition of "assistance in connection with a mutual recognition application"	(a) for "the second paragraph of Article 17.3 of the Directive 81/851/EEC" substitute: "the second paragraph of Article 32.1 of Directive 2001/82/EC" (b) for "specified in Articles 18.2 and 18.3" substitute: "specified in Article 33"
2.	After "Directive 92/74"	Add the following new definition: " 'Directive 2001/82/EC' means Directive 2001/82/EC of 6th November 2001 on the Community code relating to veterinary medicinal products;"
3.	To the definition of "EEA Agreement"	for "as amended by the Decision of the EEA Joint Committee No 7/94;" substitute: "amended as at the date of making of the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2003;"
4.	After the definition of "EEA State"	Add the following new definition: " 'export certificate' means a certificate issued under section 50 of the Act;"
5.	After the definition of "the Ministers"	Add the following new definition: " 'mutually recognised marketing authorisation' means a marketing authorisation which has a mutual recognition from a member State; "
6.	After the definition of "Regulation (EC) No 541/95"	Add the following new definition: "'Regulation (EC) No 1084/2003' means Commission Regulation (EC) No 1084/2003 of 3rd June 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;"
7.	After the definition of "relevant authority"	add the following new definitions: "'specific batch control' means consideration by the licensing 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 batch, or of a starting material used during its manufacture, differ from those detailed in the marketing authorisation or animal test certificate, so that the licensing authority may, prior to the release of the batch in question onto the market, form a view as to whether action under the 1994 Regulations would be required either to instigate a recall or to prohibit the supply of the veterinary medicinal product should the batch be placed on the market; 'starting material' means in relation to specific batch control a material required to produce the finished veterinary medicinal product for sale, and includes the finished product's container and packaging;"
8.	In the definition of "variation with extras"	after "falling within Annex II to Regulation (EC) No 541/95" add: "except in the case of a mutually recognised marketing authorisation, where it means changes falling within Annex II to Regulation (EC) No 1084/2003"

	Text	*Amendment*
9.	In the definition of "Veterinary Medicinal Product"	for "Directive 81/851/EEC" substitute "Directive 2001/82/EC"

SCHEDULE 2

Regulation 3(2)

Amendments to Schedule 1, Part I of the principal Regulations

	Text	*Amendment*
1.	In the definition of "abridged standard application"	for "Article 5.10 of Directive 81/851/EEC;" substitute "Article 13.1 of Directive 2001/82/EC;"
2.	After the definition of "active ingredient"	add the following new definitions: "'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— (a) 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; (b) a pharmaceutical veterinary medicinal product which has been authorised in a member State for use with food-producing species on whom 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 (c) 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';".
3.	In the definition of "Article 15.2 marketing authorisation"	for "of the type specified in Article 15.2 of Directive 81/851/EEC" substitute: "of the type provided for in Article 26.3 of Directive 2001/82/EC"
4.	In the definition of "immunological Veterinary Medicinal Product"	for "Directive 90/677/EEC", substitute "Directive 2001/82/EC"
5.	In the definition of "individual variation"	in sub-paragraph (a) for "Regulation (EC) No 541/95" substitute "Regulation (EC) No 1084/2003"
6.	At "mutually recognised marketing authorisation"	delete the definition
7.	In the definition of "Reference Member State"	for "Article 2.2 of Regulation (EC) No 541/95;" substitute: "Article 3.4 of Regulation (EC) No 1084/2003;"
8.	After the definition of "standard application"	for the remaining text, substitute the following definitions: "'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 "1A" is entered in the final column of that Table;

	Text	*Amendment*
		'Type IB variation' 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 "1B" is entered in the final column of that Table; 'Type II variation' means a variation of a mutually recognised marketing authorisation of the type referred to in Article 3.3 of Regulation (EC) No 1084/2003."

SCHEDULE 3

Regulation 3(2)(c)

Substitution for column (1) and new fees in columns (2) and (3) of Table F, paragraph 3, Part V, Schedule 1 to the principal Regulations, with old fees shown where applicable

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*	
Mutually recognised marketing authorisation variation type	Old fee (where applicable) £	New fee £	Old fee (where applicable) £	New fee £
Type IA Notification	—	1,515	—	230
Type IB Variation	—	2,490	—	230
Type II Variation	8,455	8,710	2,275	2,345
Variation with extras	9,670	9,960	4,045	4,165

SCHEDULE 4

Regulation 3(7)

Amendments to fees set out in the Schedules to the principal Regulations

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* *£*	*Column (4)* *New fee* *£*
SCHEDULE 1, 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**		
Paragraph 1	Marketing authorisations and product licences—		
Paragraph 1, Table A, column (2)	Fee for an application for a type A marketing authorisation—		
entry 1	Major application	20,590	21,210
entry 2	Complex application	11,945	12,305
entry 3	Standard application	5,160	5,315
entry 4	Abridged standard application	4,030	4,150
entry 5	Simple application	1,435	1,480

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* £	*Column (4)* *New fee* £
Paragraph 1 Table A, column (3)	Fee for an application for a type B marketing authorisation—		
entry 1	Major application	11,360	11,700
entry 2	Complex application	6,820	7,025
entry 3	Standard application	3,410	3,515
entry 5	Simple application	905	930
Paragraph 1, Table A, column (4)	Fee for an application for a product Licence—		
entry 1	Major application	20,590	21,210
entry 2	Complex application	11,945	12,305
entry 3	Standard application	5,160	5,315
entry 5	Simple application	1,435	1,480
Paragraph 2, Table B, column (2)	Fee for an application for an Article 26.3 marketing authorisation—		
entry 1	Major application	11,945	12,305
entry 2	Complex application	5,160	5,315
Paragraph 3	Application for a marketing authorisation by holder of Article 26.3 marketing authorisation—		
Paragraph 3(a)	Major application previously made	8,645	8,905
Paragraph 3(b)	Complex application previously made	6,785	6,990
Paragraph 6 Paragraph 6(1)(a)	Manufacturer's licences— application for manufacturer's licence in respect of products whose sale or supply does not require a marketing authorisation or product licence, etc, or emergency vaccines	100	105
Paragraph 6(1)(b)	Other cases	2,315	2,385
Paragraph 7 Paragraph 7(1)	Wholesale dealer's licences— Application fee where anticipated turnover £40,000 or more	1,345	1,385
Paragraph 7(2)	Application fee where anticipated turnover less than £40,000	550	565
Paragraph 9	Marketing authorisation (parallel import)	1,610	1,660
SCHEDULE I, PART III	**Fees relating to applications for assistance in connection with mutual recognition applications**		
Paragraph 4, Table C, column (2)	Basic fee—		
entry 1	Major	3,695	3,805
entry 2	Complex	2,470	2,545
entry 3	Standard	1,065	1,095
entry 4	Simple	360	370
Paragraph 4, Table C, column (3)	Additional fee for the sixth and each additional member State—		
entry 1	Major	800	825
entry 2	Complex	390	400
entry 3	Standard	200	205
Paragraph 5, Table D, column (2)	Basic fee		
entry 1	Category I application	9,060	9,330
entry 2	Category II application	6,050	6,230
entry 3	Category III application	4,835	4,980
Paragraph 5, Table D, column (3)	Additional fee for the sixth and each additional member State—		
entry 1	Category I application	1,135	1,170
entry 2	Category II application	760	780
entry 3	Category III application	605	625

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* £	*Column (4)* *New fee* £
SCHEDULE 1, 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**		
Paragraph 1	Application for a minor variation to a marketing authorisation (other than a mutually recognised marketing authorisation)—		
entry 1	Change in the content of the manufacturing authorisation	575	590
entry 2	Change in the name of the medicinal product (either invented name or common)	575	590
entry 3	Change in the name and/or address of the marketing authorisation holder	225	230
entry 4	Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients)	575	590
entry 5	Addition, deletion or replacement of a colorant	575	590
entry 6	Addition, deletion or replacement of a flavour	575	590
entry 7	Change in coating weight of tablets or change in weight of capsule shells	575	590
entry 8	Change in the qualitative composition of immediate packaging material	575	590
entry 9	Deletion of an indication	575	590
entry 10	Deletion of a route of administration	575	590
entry 10a	Addition or replacement of measuring device	575	590
entry 11	Change in the manufacturer(s) of active substance.	575	590
entry 11a	Change in name of manufacturer of active substance	225	230
entry 11b	Change in supplier of intermediate compound used in the manufacture	575	590
entry 12	Minor change of manufacturing process of the active substance.	575	590
entry 12a	Change in specification of starting material or intermediate used in the manufacture of the active substance	575	590
entry 13	Batch size of active substance.	575	590
entry 14	Change in specification of active substance	575	590
entry 15	Minor change in manufacture of the medicinal product	575	590
entry 15a	Change in in-process controls applied during the manufacture of the product	575	590
entry 16	Change in the batch size of finished product	575	590
entry 17	Change in specification of the medicinal product	575	590
entry 18	Synthesis or recovery of non-pharmacopoeial excipients which had been described in the original dossier	575	590
entry 19	Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	575	590
entry 20	Extension of shelf life as foreseen at time of authorisation	575	590

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* £	*Column (4)* *New fee* £
entry 20a	Extension of the shelf life or retest period of the active substance	575	590
entry 21	Change in shelf life after first opening	575	590
entry 22	Change in shelf life after reconstitution	575	590
entry 23	Change in the storage conditions	575	590
entry 24	Change in test procedure of active substance	575	590
entry 24a	Change in the test procedure for a starting material or intermediate used in the manufacture of the active substance	575	590
entry 25	Change in the test procedures of the medicinal product	575	590
entry 26	Changes to comply with supplements to pharmacopoeias	575	590
entry 27	Change in test procedures of non-pharmacopoeial excipients	575	590
entry 28	Change in test procedure of immediate packaging	575	590
entry 29	Change in test procedure of administration device	575	590
entry 30	Change in pack size for a medicinal product	575	590
entry 31	Change in container shape	575	590
entry 32	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	575	590
entry 33	Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitative composition and mean mass	575	590
entry 34	Change in the manufacturing process of a non protinaceous component due to the subsequent introduction of a biotechnology step	575	590
Paragraph 2	Application fee for any other variation to a marketing authorisation (other than a mutually recognised marketing authorisation) other than the following specified cases	2,275	2,345
entry a	Change which is made where there is identical supporting data relating to another product which is also being changed, all the products are from the same marketing authorisation holder and the change is identical to the first change and is made at the same time	225	230
entry b	Change of distributor where no other aspects of the dossier are changed and the marketing authorisation holder remains the same	225	230
entry c	Change of marketing authorisation holder where no other aspects of the dossier are changed	225	230
entry d	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 rate in mg/kg body weight remains the same	575	590

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* £	*Column (4)* *New fee* £
entry e	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	575	590
entry f	Corrections or simple text lay out changes to summary of product characteristics and/or product literature where the changes are not a result of safety, no new studies are required to support the change and no other aspects of the dossier are changed	575	590
Paragraph 5	Manufacturer's licences—		
Paragraph 5(a)	Variations covered by Part II, paragraph 6(2)	100	105
Paragraph 5(b)	Variation in any other case—		
Paragraph 5(b)(i)	Variation requiring assessment	410	425
Paragraph 5(b)(ii)	Variation not requiring assessment	140	145
Paragraph 6	Wholesale dealer's licences		
Paragraph 6(a)	Variation requiring assessment	410	425
Paragraph 6(b)	Variation not requiring assessment	140	145
Paragraph 7	Variation of animal test certificate	225	230
SCHEDULE 1, PART V	**Fees relating to applications for the renewal of marketing authorisations, product licences, manufacturer's licences and animal test certificates**		
Paragraph 1	Marketing authorisations and product licences—		
Paragraph 1(b)	Renewal of a marketing authorisation relating to a herbal product	345	355
Paragraph 1(c)	Renewal in other cases	1,025	1,055
Paragraph 2	Renewal of Manufacturer's licence	105	110
Paragraph 3	Renewal of Animal test certificate	105	110
SCHEDULE 2	**Fees relating to site inspections**		
Paragraph 2(1), Table A, column (2)			
entry 1	Supersite inspection	9,525	9,810
entry 2	Major inspection	5,010	5,160
entry 3	Standard inspection	3,590	3,700
entry 4	Minor inspection	1,935	1,995
Paragraph 2(2), Table B, column (2)			
entry 1	Supersite inspection	15,795	16,270
entry 2	Major inspection	8,730	8,990
entry 3	Standard inspection covering immunological Veterinary Medicinal Products	5,695	5,865
entry 4	Other standard inspection	4,290	4,420
entry 5	Minor inspection covering immunological Veterinary Medicinal Products	2,870	2,955
entry 6	Other minor inspection	2,870	2,955
Paragraph 2(3), Table C, column (2)			
entry 1	Supersite inspection	6,920	7,130
entry 2	Major inspection	4,675	4,815

Column (1) *Provision of the Medicines (Products for Animal Use—Fees) Regulations 1998*	*Column (2)* *Subject matter*	*Column (3)* *Old fee* £	*Column (4)* *New fee* £
entry 3	Standard inspection	2,290	2,360
entry 4	Minor inspection	1,185	1,220
Paragraph 2(4)(a)	Inspection of site limited solely to manufacture or assembly of products whose sale or supply does not require a marketing authorisation or product licence, etc	100	105
Paragraph 3(1)	Inspection of either or both of premises and procedures for quality control of a biological product which is not a dormant product	1,370	1,410
Paragraph 3(2)	Inspection in connection with an authorised or licensed biological product (other than a dormant biological product) granted a marketing authorisation etc because it was identical to an existing product	55	60
SCHEDULE 5, PART II	**Fees relating to applications for registration of homoeopathic veterinary medicinal products**		
Paragraph 1, Table, Column (2)	Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks—		
entry 1	Product both prepared solely from repeat stock and being of repeat formulation	120	125
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	345	355
entry 3	Any other application	575	590
Paragraph 1, Table, column (3)	Fees for applications in respect of products prepared from more than 5 homoeopathic stocks—		
entry 1	Product both prepared solely from repeat stock and being of repeat formulation	280	290
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	505	520
entry 3	Any other application	740	760
Paragraph 2	Equivalent product registered under Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 or in an EEA State—		
Paragraph 2(i)	Product prepared from not more than 5 homoeopathic stocks	120	125
Paragraph 2(ii)	Product prepared from more than 5 homoeopathic stocks	280	290
SCHEDULE 6	**Marketing authorisations, product licences, and animal test certificates: fees for references to the Veterinary Products Committee or to the Medicines Commission**		
Paragraph 1, Table, column (2)			
entry 1	Major application	1,620	1,670
entry 2	Complex application	930	960
entry 3	Standard application	430	445
entry 4	Simple application	165	170
Paragraph 2	Animal test certificate	565	580

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Products for Animal Use—Fees) Regulations 1998 (S.I. 1998/2428), which 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 granted under the Medicines Act 1968 in so far as they apply to medicinal products for animal use; and

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

Regulations 2 and 3 and Schedules 3 and 4 prescribe new fees in relation to the provisions specified there, with the previous fee shown as a comparison. Most fees payable under these Regulations are increased by 3 per cent (rounded up or down to the nearest £5) in comparison with the 1998 Regulations as last amended.

New charges are introduced and fees set for applications for export certificates (issued under the Medicines Act 1968) and for requests to the licensing authority to carry out specific batch control (regulation 2(2) and (3) and 3(2)(b)(iv)). Charging for referrals of variations with extras falling under regulation 9 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 is brought into line with other variations with extras referred to the Veterinary Products Committee (regulation 3(5)). Amendment is also made to reflect changes in the category of Animal Test Certificate applications (regulation 3(2)(a) and (b)(iii)).

The Regulations also introduce new fees to reflect amendments to the arrangements for processing of applications for variations to mutually recognised marketing authorisations required by recent changes in EC law (see Commission Regulation (EC) No 1084/2003) (regulation 2(2), 3(2)(a) and (c)). References to EC legislation have where appropriate been updated throughout.

Regulation 4 (transitional arrangements) provides that the Regulations, subject to the exceptions in paragraphs (2) and (3) of that regulation, apply to applications made after the Regulations come into force and that, for fees relating to turnover, the first relevant year is 2002.

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

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