STATUTORY INSTRUMENTS

1999 No. 2512

MEDICINES

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

Made - - - -	*9th September 1999*
Laid before Parliament	*10th September 1999*
Coming into force - -	*1st October 1999*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of the powers conferred by section 1(1), (2) and (3)(b) of the Medicines Act 1971[F1] and now vested in them[F2] and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations[F3], and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated[F4] for the purpose of section 2(2) of the European Communities Act 1972[F5] in relation to medicinal products and the common agricultural policy of the European Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

F1 1971 c. 69 as amended by section 21 of the Health and Medicines Act 1988 (c. 49); by virtue of section 1(3) of the 1971 Act expressions in that section have the same meaning as in the Medicines Act 1968 (c. 67) as amended by the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388). The expression “the Ministers" is defined in section 1(1) of the 1968 Act as so amended.

F2 In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969; in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No.1) Order 1978 (S.I. 1978/272); in the case of Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

F3 *See* section 129(6) of the Medicines Act 1968 as extended to include Regulations made under the Medicines Act 1971 by section 1(3)(b) of that latter Act.

F4 S.I. 1972/1811.

F5 1972 c. 68.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Animal Use—Fees) Amendment Regulations 1999 and shall come into force on 1st October 1999.

(2) In these Regulations "the principal Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1998 [F6].

(3) Unless the context otherwise requires, expressions used in these Regulations shall have the same meaning as in the principal Regulations.

F6 S.I. 1998/2428.

Amendment of fees specified in the principal Regulations

2. In respect of each provision of the principal Regulations specified in the entries in column (1) (the subject matter of which is described in column (2)) of the Schedule to these Regulations, where a fee is specified opposite that provision in column (3) there shall be substituted the fee specified opposite that provision in column (4).

3.—(1) In Schedule 3 to the principal Regulations—

(a) in Part II, paragraph 1 (calculation of annual fees) there shall be substituted the figure " £262 " for the figure "£248", the figure " £18,480 " for the figure "£17,640", and the figure " 0.44%. " for the figure "0.42%.";

(b) in Part II, paragraph 2 (calculation of annual fees) there shall be substituted the figure " 0.66% " for the figure "0.63%"; and

(c) in Part III (calculation of annual fee—emergency vaccines) there shall be substituted the figure " 0.66% " for the figure "0.63%".

Transitional provisions

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

(2) These Regulations shall apply in relation to any fee payable in respect of any inspection made after these Regulations come into force in connection with any application made before they come into force.

(3) Where, in connection with an application to renew a marketing authorisation, licence or certificate made before these Regulations come into force, the authorisation, licence or certificate is due to expire on or after the date these Regulations come into force, regulation 17(4) and (5) of the principal Regulations shall apply to that application on the basis that the fee payable for the application following the coming into force of these Regulations is the appropriate fee payable.

(4) Nothing in these Regulations shall have effect in relation to an annual fee relating to a calendar year earlier than 1998.

Signed by authority of Secretary of State for Health

Gisela Stuart
Parliamentary Under Secretary of State,
31st August 1999 Department of Health

Signed by authority of the Secretary of State for Wales

David Hanson
Parliamentary Under Secretary of State, Welsh
9th September 1999 Office

John Reid
Parliamentary Under Secretary of State, Scottish
1st September 1999 Office

Joyce Quin
Minister of State, Ministry of Agriculture,
26th August 1999 Fisheries and Food

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

D. C. Gowdy
1st day of September 1999 Permanent Secretary

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

P. J. Small
1st day of September 1999 Permanent Secretary

We consent,

Bob Ainsworth
Jim Dowd
Two of the Lords Commissioners of Her Majesty's Treasury

1st September 1999

SCHEDULE

Regulation 2

SUBSTITUTION OF FEES

Column (1) Provision in the principal Regulations	*Column (2) Subject matter*	*Column (3) Old fee*	*Column (4) New fee*
regulation 12	Manufacturer's licences: annual fees	£190	£200
regulation 13	Wholesale dealer's licences: annual fees		
regulation 13(1)	Turnover of £40,000 or more	£380	£400
regulation 13(2)	Turnover of less than £40,000	£185	£200
regulation 14	Registration of Homoeopathic Veterinary Medicinal Products		
regulation 14(2)	Renewal of registration	£75	£80
regulation 14(3)	Alteration of dossier	£85	£90
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, Table A, Column (2)	Fee for an application for a type A marketing authorisation		
entry 1	Major application	£18,120	£19,115
entry 2	Complex application	£10,515	£11,095
entry 3	Standard application	£4,540	£4,790
entry 4	Abridged standard application	£3,545	£3,740
entry 5	Simple application	£1,260	£1,330
paragraph 1, Table A, Column (3)	Fee for an application for a type B marketing authorisation		
entry 1	Major application	£10,000	£10,550
entry 2	Complex application	£6,000	£6,330
entry 3	Standard application	£3,000	£3,165
entry 5	Simple application	£800	£845
paragraph 1, Table A, Column (4)	Fee for an application for a product licence		
entry 1	Major application	£18,120	£19,115
entry 2	Complex application	£10,515	£11,095

entry 3	Standard application	£4,540	£4,790
entry 5	Simple application	£1,260	£1,330
paragraph 2, Table B, Column (2)	Fee for an application for an Article 15.2 marketing authorisation		
entry 1	Major application	£10,515	£11,095
entry 2	Complex application	£4,540	£4,790
paragraph 3	Application for a marketing authorisation by holder of Article 15.2 marketing authorisation		
paragraph 3(a)	Major application previously made	£7,605	£8,020
paragraph 3(b)	Complex application previously made	£5,975	£6,305
paragraph 6	Manufacturer's licences		
paragraph 6(1)(a)	Applications in respect of which paragraph 6(2) applies	£95	£100
paragraph 6(1)(b)	Other cases	£2,040	£2,150
paragraph 7	Wholesale dealer's licences		
paragraph 7(1)	Application fee where anticipated turnover £40,000 or more	£1,185	£1,250
paragraph 7(2)	Application fee where anticipated turnover less than £40,000	£480	£505
paragraph 8	Animal test certificate applications in relation to biological products or for administration to non food-producing animals	£250	£265
paragraph 8	Other animal test certificate applications	£600	£635
paragraph 9	Marketing authorisation (parallel import)	£1,415	£1,495
SCHEDULE 1,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	£3,250	£3,430
entry 2	Complex	£2,175	£2,295

entry 3	Standard	£940	£990
entry 4	Simple	£315	£330
paragraph 4, Table C, Column (3)	Additional fee for the sixth and each additional member State		
entry 1	Major	£700	£740
entry 2	Complex	£340	£360
entry 3	Standard	£175	£185
entry 4	Simple	£60	£65
paragraph 5, Table D, Column (2)	Basic fee		
entry 1	Category I application	£7,975	£8,415
entry 2	Category II application	£5,320	£5,615
entry 3	Category III application	£4,255	£4,490
paragraph 5, Table D, Column (3)	Additional fee for the sixth and each additional member State		
entry 1	Category I application	£1,000	£1,055
entry 2	Category II application	£665	£700
entry 3	Category III application	£530	£560
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	Marketing authorisations (other than mutually recognised marketing authorisations) and product licences—complex application for variation	£2,000	£2,110
paragraph 2, Table E, Column (2)	Marketing authorisations (other than mutually recognised marketing authorisations) and product licences—application for variation other than complex application		
entry 1	Variation requiring assessment	£500	£530
entry 2	Variation not requiring assessment	£200	£210
paragraph 3, Table F, Column (2)	United Kingdom acting as the Reference Member State		

entry 1	Type I variation—Administrative	£530	£560
entry 2	Type I variation, Scientific—	£2,130	£2,245
entry 3	Type I variation, Scientific—	£3,500	£3,695
	Type II procedure		
entry 4	Type II variation	£7,445	£7,855
entry 5	Variation with extras	£8,510	£8,980
paragraph 3, Table F, Column (3)	United Kingdom not acting as the Reference Member State		
entry 1	Type I variation—Administrative	£100	£105
entry 2	Type I variation—Scientific	£500	£530
entry 3	Type I variation, Scientific-Type II procedure	£1,000	£1,055
entry 4	Type II variation	£2,000	£2,110
entry 5	Variation with extras	£3,560	£3,755
paragraph 5	Manufacturer’s licences		
paragraph 5(a)	Variation of manufacturer’s licence referred to in Schedule 1, Part II, paragraph 6(2)	£95	£100
paragraph 5(b)	Variation in any other case		
paragraph 5(b)(i)	Requiring assessment	£360	£380
paragraph 5(b)(ii)	Not requiring assessment	£120	£125
paragraph 6	Wholesale dealer’s licences		
paragraph 6(a)	Variation requiring assessment	£360	£380
paragraph 6(b)	Variation not requiring assessment	£120	£125
paragraph 7	Variation of animal test certificate	£200	£210

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)	Herbal products	£300	£315
paragraph 1(c)	Other cases	£900	£950
paragraph 2	Manufacturer's licences	£90	£95
paragraph 3	Animal test certificates	£90	£95
SCHEDULE 2	FESS REALTING TO SITE INSPECTIONS		
paragraph 2(1), Table A, Column (2)			
entry 1	Supersite inspection	£8,390	£8,850
entry 2	Major inspection	£4,415	£4,655
entry 3	Standard inspection	£3,155	£3,330
entry 4	Minor inspection	£1,705	£1,800
paragraph 2(2), Table B, Column (2)			
entry 1	Supersite inspection	£13,905	£14,670
entry 2	Major inspection	£7,680	£8,100
entry 3	Standard inspection covering immunological Veterinary Medicinal Products	£5,010	£5,285
entry 4	Other standard inspection	£3,775	£3,985
entry 5	Minor inspection covering immunological Veterinary Medicinal Products	£2,580	£2,720
entry 6	Other minor inspection	£2,525	£2,665
paragraph 2(3), Table C, Column (2)			
entry 1	Supersite inspection	£6,090	£6,425
entry 2	Major inspection	£4,115	£4,340
entry 3	Standard inspection	£2,015	£2,125
entry 4	Minor inspection	£1,035	£1,095
paragraph 2(4)(b)	Site limited solely to manufacture and assembly of emergency vaccines	£100	£105
paragraph 3(1)	Either or both of premises and procedures for quality control of a biological	£1,210	£1,275

	product which is not a dormant product		
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	£100	£105
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	£300	£315
entry 3	Any other application	£500	£530
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	£250	£265
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	£450	£475
entry 3	Any other application	£650	£685
paragraph 2	Equivalent product registered under Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 [F7]		
	or in an EEA State		
paragraph 2(i)	Product prepared from not more than 5 homoeopathic stocks	£100	£105
paragraph 2(ii)	Product prepared from more than 5 homoeopathic stocks	£250	£265
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	£1,420	£1,500
entry 2	Complex application	£820	£865
entry 3	Standard application	£380	£400

entry 4	Simple application	£140	£150
paragraph 2	Animal test certificate	£495	£520

F7 S.I. 1994/105, amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574.

EXPLANATORY NOTE

(This note is not part of the Regulations)
These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 1998 ("the principal Regulations"). The principal Regulations 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.

In prescribing fees in relation to the 1994 Regulations, the principal Regulations as amended by these Regulations continue to supplement the 1994 Regulations in implementing Council Directive 93/40/EEC (OJ No. L214, 24.8.93, page 31) which contains amendments to Council Directive 81/851/EEC (OJ No. L317, 6.11.81, page 1).
Regulation 2 prescribes new fees in relation to the provisions of the principal Regulations set out in column (1) of the Schedule to these Regulations. The fees in the principal Regulations are set out in column (3) and the new fees prescribed by these Regulations in column (4) of the Schedule.
Regulation 3 amends Parts II and III of Schedule 3 (calculation of annual fees) to the principal Regulations by prescribing new fees and, where the fee is charged on a percentage of turnover, new percentage amounts.
The average level of fees payable under these Regulations is increased by 5.5% in comparison with the principal Regulations.
Regulation 4 provides that the Regulations, subject to the exceptions in regulation 4(2) and (3), apply to applications made after the Regulations come into force and do not affect annual fees relating to a calendar year earlier than 1998.
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, New Haw, Addlestone, Surrey, KT15 3LS.

Status:
Point in time view as at 01/10/1999.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines (Products for Animal Use—Fees) (Amendment) Regulations 1999. Any changes that have already been made by the team appear in the content and are referenced with annotations.