STATUTORY INSTRUMENTS

2001 No. 3751

MEDICINES

Medicines (Products for Animal Use—Fees) (Amendment No. 2) Regulations 2001

Made - - - -	*22nd November 2001*
Laid before Parliament	*23rd November 2001*
Coming into force - -	*15th December 2001*

The Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England, the Minister of Health, Social Services and Public Safety and the Minister 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[M1] and now vested in them[M2] 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[M3], and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated for the purpose of section 2(2) of the European Communities Act 1972[M4] 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), make the following Regulations—

Marginal Citations

M1 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 article 2(2) of, and Schedule 1 to, 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.

M2 In the case of the Minister of Agriculture, Fisheries and Food (so far as concerns functions previously vested in the Secretaries of State respectively concerned with agriculture in Scotland and—in consequence of S.I. 1978/272—Wales), by virtue of articles 2(2) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142); in the case of the Secretary of State concerned with health in England (so far as concerns functions previously vested in the Secretaries of State respectively concerned with health in Scotland and—in consequence of S.I. 1969/388—Wales), by virtue of articles 2(1) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999; in the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, 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)).

M3 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.

M4 S.I. 1972/1811.

Title, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products of Animal Use—Fees) (Amendment No. 2) Regulations 2001 and shall come into force on 15th December 2001.

(2) In these Regulations "the Principal Regulations" means the Medicines (Products for Animal Use—Fees) Regulations 1998 [M5].

Marginal Citations

M5 S.I. 1998/2428 as amended by S.I. 2000/2250 and S.I. 2001/1669.

Amendment of fees specified in the principal Regulations

2.—(1) 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 Part I 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).

(2) Paragraphs 1 and 2 of Part IV of the principal Regulations shall be replaced with the provisions of Part II of the Schedule to these Regulations.

(3) In Schedule 3 to the principal Regulations—

(a) in Part II, paragraph 1 (calculation of annual fees) there shall be substituted the figure "£275" for the figure " £269 ", the figure "£19,600" for the figure " £18,956 ", and the figure "0.46%" for the figure " 0.451%. ";

(b) in Part II, paragraph 2 (calculation of annual fees) there shall be substituted the figure "0.7%" for the figure " 0.677% "; and

(c) in Part III (calculation of annual fee—emergency vaccines) there shall be substituted the figure "0.7%" for the figure " 0.677% ".

Transitional provisions

3.—(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 2000.

Whitty
Parliamentary Under Secretary of State Ministry
22 November 2002 of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State
16 November 2001 Department of Health

Bairbre De Brún
Minister of Health, Social Services and Public
21 November 2001 Safety

Brid Rodgers
19 November 2001 Minister of Agriculture and Rural Development

We consent

Nick Ainger
Tony McNulty
Two of the Lords Commissioners of Her
19 November 2001 Majesty's Treasury

SCHEDULE Regulation 2

PART I

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	205	210
Regulation 13	Wholesale dealer's licences: annual fees		
Regulation 13(1)	Turnover of £40,000 or more	410	420
Regulation 13(2)	Turnover of less than £40,000	205	210
Regulation 14	Registration of Homoeopathic Veterinary Medicinal Products		
Regulation 14(3)	Alteration of dossier	90	95
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	19,595	20,085
Entry 2	Complex application	11,370	11,655
Entry 3	Standard application	4,910	5,035
Entry 4	Abridged standard application	3,835	3,930
Entry 5	Simple application	1,385	1,400

Paragraph 1, Table A, Column (3)	Fee for an application for a type B marketing authorisation		
Entry 1	Major application	10,815	11,085
Entry 2	Complex application	6,490	6,655
Entry 3	Standard application	3,245	3,325
Entry 5	Simple application	865	885
Paragraph 1, Table A, Column (4)	Fee for an application for a product licence		
Entry 1	Major application	19,595	20,085
Entry 2	Complex application	11,370	11,655
Entry 3	Standard application	4,910	5,035
Entry 5	Simple application	1,365	1,400
Paragraph 2, Table B, Column (2)	Fee for an application for an Article 15.2 marketing authorisation		
Entry 1	Major application	11,370	11,655
Entry 2	Complex application	4,910	5,035
Paragraph 3	Application for a marketing authorisation by holder of Article 15.2 marketing authorisation		
Paragraph 3(a)	Major application previously made	8,225	8,430
Paragraph 3(b)	Complex application previously made	6,460	6,620
Paragraph 6	Manufacturer’s licences		
Paragraph 6(1)(b)	Other cases	2,205	2,260
Paragraph 7	Wholesale dealer’s licences		
Paragraph 7(1)	Application fee where anticipated turnover £40,000 or more	1,280	1,310
Paragraph 7(2)	Application fee where anticipated turnover less than £40,000	520	535
Paragraph 8	Animal test certificate applications in relation	270	275

	to biological products or for administration to non food-producing animals		
Paragraph 8	Other animal test certificate applications	650	665
Paragraph 9	Marketing authorisation (parallel import)	1,530	1,570
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	3,515	3,605
Entry 2	Complex	2,350	2,410
Entry 3	Standard	1,015	1,040
Entry 4	Simple	340	350
Paragraph 4, Table C, Column (3)	Additional fee for the sixth and each additional member State		
Entry 1	Major	760	780
Entry 2	Complex	370	380
Entry 3	Standard	190	195
Paragraph 5, Table D, Column (2)	Basic Fee		
Entry 1	Category I application	8,625	8,840
Entry 2	Category II application	5,755	5,900
Entry 3	Category III application	4,600	4,715
Paragraph 5, Table D, Column (3)	Additional fee for the sixth and each additional member State		
Entry 1	Category I application	1,080	1,105
Entry 2	Category II application	720	740
Entry 3	Category III application	575	590

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 3, Table F, Column (2)	United Kingdom acting as the Reference Member State		
Entry 1	Type I variation—Administrative	575	590
Entry 2	Type I variation—Scientific	2,300	2,360
Entry 3	Type 1 variation, Scientific—Type II procedure	3,785	3,880
Entry 4	Type II variation	8,050	8,250
Entry 5	Variation with extras	9,205	9,435
Paragraph 3, Table F, Column (3)	United Kingdom not acting as the Reference Member State		
Entry 1	Type I variation—Administrative	110	115
Entry 2	Type I variation—Scientific	545	560
Entry 3	Type I variation, Scientific—Type II procedure	1,080	1,105
Entry 4	Type II variation	2,165	2,220
Entry 5	Variation with extras	3,850	3,945
Paragraph 5	Manufacturer's licences		
Paragraph 5(b)	Variation in any other case		
Paragraph 5(b)(i)	Requiring assessment	390	400

Paragraph 5(b)(ii)	Not requiring assessment	130	135
Paragraph 6	Wholesale dealer's licences		
Paragraph 6(a)	Variation requiring assessment	390	400
Paragraph 6(b)	Variation not requiring assessment	130	135
Paragraph 7	Variation of animal test certificate	215	220
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	325	335
Paragraph 1(c)	Other cases	975	1,000
Paragraph 2	Manufacturer's licences	95	100
Paragraph 3	Animal test certificates	95	100
SCHEDULE 2	FEES RELATING TO SITE INSPECTIONS		
Paragraph 2(1), Table A, Column (2)			
Entry 1	Supersite inspection	9,070	9,295
Entry 2	Major inspection	4,770	4,890
Entry 3	Standard inspection	3,415	3,500
Entry 4	Minor inspection	1,845	1,890
Paragraph 2(2), Table B, Column (2)			
Entry 1	Supersite inspection	15,035	15,410
Entry 2	Major inspection	8,305	8,515
Entry 3	Standard inspection covering immunological	5,420	5,555

	Veterinary Medicinal Products		
Entry 4	Other standard inspection	4,085	4,185
Entry 5	Minor inspection covering immunological Veterinary Medicinal Products	2,730	2,800
Entry 6	Other minor inspection	2,730	2,800
Paragraph 2(3), Table C, Column (2)			
Entry 1	Supersite inspection	6,585	6,750
Entry 2	Major inspection	4,450	4,560
Entry 3	Standard inspection	2,180	2,235
Entry 4	Minor inspection	1,125	1,155
Paragraph 3(1)	Either or both of premises and procedures for quality control of a biological product which is not a dormant product	1,305	1,335
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	110	115
Entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	325	335
Entry 3	Any other application	545	560
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	270	275
Entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	485	495
Entry 3	Any other application	700	720
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	110	115
Paragraph 2(ii)	Product prepared from more than 5 homoeopathic stocks	270	275
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	1,540	1,580
Entry 2	Complex application	885	905
Entry 3	Standard application	410	420
Entry 4	Simple application	155	160
Paragraph 2	Animal test certificate	535	550

PART II

REPLACEMENT OF PARAGRAPHS 1 AND 2 OF PART IV OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS

1. The application fee for a minor variation (Type 1) to a marketing authorisation (other than a mutually recognised marketing authorisation) as referred to in Annex 1 to Commission Regulation (EC) No. 541/95 (concerning the examination of variations to the terms of a marketing authorisation granted by a competent authority of a member State [M6]) shall be as follows:—

	Type of application	***Fee £***
1.	Change following modification(s) to the manufacturing authorisation	560
2.	Change in the name of the medicinal product (either invented name or common name)	560
3.	Change in the name and/or address of the marketing authorisation holder	220
4.	Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients)	560
5.	Change in the colouring system of the product (addition, deletion or replacement of colourant(s))	560
6.	Change in the flavouring system of the product (addition, deletion or replacement of flavour(s))	560
7.	Change in coating weight of tablets or change in weight of capsule shells	560
8.	Change in the qualitative composition of immediate packaging material	560
9.	Deletion of an indication	560
10.	Deletion of a route of administration	560
10a.	Addition or replacement of measuring device for dosage forms	560

11.	Change in the manufacturer(s) of active substance	560
11a.	Change in name of manufacturer of active substance	220
11b.	Change in supplier of intermediate compound used in the manufacture of the active substance	560
12	Minor change of manufacturing process of the active substance	560
12a.	Change in specification of starting material or intermediate used in the manufacture of the active substance	560
13.	Batch size of active substance	560
14.	Change in specification of active substance	560
15.	Minor change in manufacture of the medicinal product	560
15a.	Change in in-process controls applied during the manufacture of the product	560
16.	Change in the batch size of finished product	560
17.	Change in specification of the medicinal product	560
18.	Synthesis or recovery of non-pharmacopoeial excipients which had been described in the original dossier	560
19.	Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	560
20.	Extension of shelf life as foreseen at time of authorisation	560
20a.	Extension of the shelf life or retest period of the active substance	560
21.	Change in shelf life after first opening	560

22.	Change in shelf life after reconstitution	560
23.	Change in the storage conditions	560
24.	Change in test procedure of active substance	560
24a.	Change in test procedure for a starting material or intermediate used in the manufacture of the active substance	560
25.	Change in the test procedures of the medicinal product	560
26.	Changes to comply with supplements to pharmacopoeias	560
27.	Change in test procedures of non-pharmacopoeial excipients	560
28.	Change in test procedure of immediate packaging	560
29.	Change in test procedure of administrative device	560
30.	Change in pack size for a medicinal product	560
31.	Change in container shape	560
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	560
33.	Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitive composition and mean mass	560
34.	Change in the manufacturing process of a non proteinaceous component due to the subsequent introduction of a biotechnology step	560

Marginal Citations

M6 OJ No. L55, 11.3.95, p. 7 as last amended by Commission Regulation (EC) No. 1146/98, OJ No. L159, 3.6.98, p.31.

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 £2,220 except in the following cases, where the fee shall be the amount specified:—

	Type of application	*Fee £*
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	220
b.	Change of distributor where no other aspects of the dossier are changed and the marketing authorisation holder remains the same	220
c.	Change of marketing authorisation holder where no other aspects of the dossier are changed	220
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	560
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	560
f.	Corrections or simple text lay out changes to summary of product characteristics and/or product literature	560

	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

2A. Notwithstanding the above, the fee for a variation where the licence relates solely to an emergency vaccine shall be £40 for each variation.

EXPLANATORY NOTE

(This note is not part of the Regulations)
These Regulations amend the Medicines (Products for Animal Use—Fees) Regulations 1998 (S.I. 1998/2428) as amended by the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2000 (S.I. 2000/2250) and the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2001 (S.I. 2001/1669) ("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.

Regulation 2 prescribes new fees in relation to the provision 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.
It also amends Part 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 2.5% in comparison with the principal Regulations.
Regulation 3 provides that the Regulations, subject to the exceptions in regulation 3(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 2000.
The fee structure relating to variations for national marketing authorisations has been restructured to reflect operational procedures (Part II of the Schedule).
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.

Status:
Point in time view as at 15/12/2001.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Medicines (Products for Animal Use—Fees) (Amendment No. 2) Regulations 2001. Any changes that have already been made by the team appear in the content and are referenced with annotations.