2002 No. 2569

MEDICINES

Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2002

Made - - - - -	*10th October 2002*
Laid before Parliament	*11th October 2002*
Coming into force - -	*1st November 2002*

The Secretary of State for Environment, Food and Rural Affairs, the Minister for 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(**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 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;

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)(**e**);

Make the following Regulations—

(**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. These are now the Secretary of State and the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development acting jointly.

In the case of the Secretary of State, this is by virtue of—

(i) article 2(2) of, and paragraph 1 of the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142), which transferred to the Minister of Agriculture, Fisheries and Food the functions of—

(aa) the Secretary of State concerned with agriculture in Scotland and

(bb) the functions of the Secretary of State for Wales which were exercisable by him by virtue of the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); and

(ii) 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) the effect of which was to transfer to the Secretary of State the functions of the Minister of Agriculture, Fisheries and Food and to remove the reference to the Secretary of State concerned with Health in England from the definition of "the Ministers".

In the case of the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, this is by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Nothern 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**) OJ No. L31, 1.2 2002, p. 1.

Title, commencement and interpretation

1. These Regulations may be cited as the Medicines (Products for Animal Use—Fees) (Amendment) Regulations 2002 and shall come into force on 1st November 2002.

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

2.—(1) In the Schedule, in respect of each provision of the Medicines (Products for Animal Use—Fees) Regulations 1998(**a**) specified in column (1), the fee in column (4) is substituted for the fee in column (3).

(2) In Schedule 3 to those Regulations—

(a) in Part II, paragraph 1 (calculation of annual fees) there shall be substituted the figure "£280" for the figure "£275", the figure "£19,880" for the figure "£19,600", and the figure "0.47%" for the figure "0.46%";

(b) in Part II, paragraph 2 (calculation of annual fees) there shall be substituted the figure "0.71%" for the figure "0.7%"; and

(c) in Part III (calculation of annual fee—emergency vaccines) there shall be substituted the figure "0.71%" for the figure "0.7%".

Transitional provisions

3.—(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 2001 and are still payable.

Elliot Morley
Parliamentary Under Secretary of State
4th October 2002 Department for Environment, Food and Rural Affairs

Bairbre De Brun
Minister of Health, Social Services and
9th October 2002 Public Safety

Brid Rodgers
Minister of Agriculture and
4th October 2002 Rural Development

We consent

John Heppell
Jim Fitzpatrick
10th October 2002 Two of the Lords Commissioners of Her Majesty's Treasury

(**a**) S.I. 1998/2428 as amended by S.I. 2000/2250, S.I. 2001/1669 and S.I. 2001/3751.

SCHEDULE

Regulation 2

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** **£**
Regulation 12	Manufacturer's licences: annual fees	210	215
Regulation 13	Wholesale dealer's licences: annual fees		
Regulation 13(1)	Turnover of £40,000 or more	420	430
Regulation 13(2)	Turnover of less than £40,000	210	215
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	20,085	20,590
entry 2	Complex application	11,655	11,945
entry 3	Standard application	5,035	5,160
entry 4	Abridged standard application	3,930	4,030
entry 5	Simple application	1,400	1,435
Paragraph 1, Table A, column (3)	Fee for an application for a type B marketing authorisation		
entry 1	Major application	11,085	11,360
entry 2	Complex application	6,655	6,820
entry 3	Standard application	3,325	3,410
entry 5	Simple application	885	905
Paragraph 1, Table A, column (4)	Fee for an application for a product licence		
entry 1	Major application	20,085	20,590
entry 2	Complex application	11,655	11,945
entry 3	Standard application	5,035	5,160
entry 5	Simple application	1,400	1,435
Paragraph 2, Table B, column (2)	Fee for an application for an Article 15.2 marketing authorisation		
entry 1	Major application	11,655	11,945
entry 2	Complex application	5,035	5,160
Paragraph 3	Application for a marketing authorisation by holder of Article 15.2 marketing authorisation		
Paragraph 3(a)	Major application previously made	8,430	8,645
Paragraph 3(b)	Complex application previously made	6,620	6,785
Paragraph 6	Manufacturer's licences		
Paragraph 6(1)(b)	Other cases	2,260	2,315
Paragraph 7	Wholesale dealer's licences		
Paragraph 7(1)	Application fee where anticipated turnover £40,000 or more	1,310	1,345
Paragraph 7(2)	Application fee where anticipated turnover less than £40,000	535	550
Paragraph 8	Animal test certificate applications in relation to biological products or for administration to non-food producing animals	275	280
Paragraph 8	Other animal test certificate applications	665	680
Paragraph 9	Marketing authorisation (parallel import)	1,570	1,610
SCHEDULE 1, PART III	**Fees relating to applications for assistance in connection with mutual recognition applications**		
Paragraph 4, Table C, column (2)	Basic Fee		

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 1	Major	3,605	3,695
entry 2	Complex	2,410	2,470
entry 3	Standard	1,040	1,065
entry 4	Simple	350	360
Paragraph 4, Table C, column (3)	Additional fee for the sixth and each additional member State		
entry 1	Major	780	800
entry 2	Complex	380	390
entry 3	Standard	195	200
Paragraph 5, Table D, column (2)	Basic Fee		
entry 1	Category I application	8,840	9,060
entry 2	Category II application	5,900	6,050
entry 3	Category III application	4,715	4,835
Paragraph 5, Table D, column (3)	Additional fee for the sixth and each additional member State		
entry 1	Category I application	1,105	1,135
entry 2	Category II application	740	760
entry 3	Category III application	590	605
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		
entry 1	Changes in the content of the manufacturing authorisation	560	575
entry 2	Change in the name of the medicinal product (either invented name or common)	560	575
entry 3	Change in the name and/or address of the marketing authorisation holder	220	225
entry 4	Replacement of an excipient with a comparable excipient (excluding adjuvants for vaccines and biologically derived excipients)	560	575
entry 5	Addition, deletion or replacement of a colorant	560	575
entry 6	Addition, deletion or replacement of a flavour	560	575
entry 7	Change in coating weight of tablets or change in weight of capsule shells	560	575
entry 8	Change in the qualitative composition of immediate packaging material	560	575
entry 9	Deletion of an indication	560	575
entry 10	Deletion of a route of administration	560	575
entry 10a	Addition or replacement of measuring device	560	575
entry 11	Change in the manufacturer(s) of active substance	560	575
entry 11a	Change in name of manufacturer of active substance	220	225
entry 11b	Change in supplier of intermediate compound used in the manufacture	560	575
entry 12	Minor change of manufacturing process of the active substance	560	575

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 12a	Change in specification of starting material or intermediate used in the manufacture of the active substance	560	575
entry 13	Batch size of active substance	560	575
entry 14	Change in specification of active substance	560	575
entry 15	Minor change in manufacture of the medicinal product	560	575
entry 15a	Change in in-process controls applied during the manufacture of the product	560	575
entry 16	Change in the batch size of finished product	560	575
entry 17	Change in specification of the medicinal product	560	575
entry 18	Synthesis or recovery of non-pharmacopoeial excipients which had been described in the original dossier	560	575
entry 19	Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	560	575
entry 20	Extension of shelf life as foreseen at time of authorisation	560	575
entry 20a	Extension of the shelf life or retest period of the active substance	560	575
entry 21	Change in shelf life after first opening	560	575
entry 22	Change in shelf life after reconstitution	560	575
entry 23	Change in the storage conditions	560	575
entry 24	Change in test procedure of active substance	560	575
entry 24a	Change in the test procedure for a starting material or intermediate used in the manufacture of the active substance	560	575
entry 25	Change in the test procedures of the medicinal product	560	575
entry 26	Changes to comply with supplements to pharmacopoeias	560	575
entry 27	Change in test procedures of non-pharmacopoeial excipients	560	575
entry 28	Change in test procedure of immediate packaging	560	575
entry 29	Change in test procedure of administration device	560	575
entry 30	Change in pack size for a medicinal product	560	575
entry 31	Change in container shape	560	575
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	560	575
entry 33	Change of dimensions of tablets, capsules, suppositories or pessaries without change of quantitative composition and mean mass	560	575

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 34	Change in the manufacturing process of a non protinaceous component due to the subsequent introduction of a biotechnology step	560	575
Paragraph 2	Application fee for any other variation other than the following specified cases	2,220	2,275
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	220	225
entry b	Change of distributor where no other aspects of the dossier are changed and the marketing authorisation holder remains the same	220	225
entry c	Change of marketing authorisation holder where no other aspects of the dossier are changed	220	225
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	560	575
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	560	575
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	560	575
Paragraph 3, Table F, column (2)	United Kingdom acting as the Reference Member State		
entry 1	Type I variation—Administrative	590	605
entry 2	Type I variation, Scientific	2,360	2,420
entry 3	Type I variation, Scientific—Type II procedure	3,880	3,975
entry 4	Type II variation	8,250	8,455
entry 5	Variation with extras	9,435	9,670
Paragraph 3, Table F, column (3)	United Kingdom not acting as the Reference Member State		
entry 1	Type I variation—Administration	115	120
entry 2	Type I variation—Scientific	560	575
entry 3	Type I variation, Scientific—Type II procedure	1,105	1,135
entry 4	Type II variation	2,220	2,275
entry 5	Variation with extras	3,945	4,045

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 5	Manufacturer's licences		
Paragraph 5(b)	Variation in any other case		
Paragraph 5(b)(i)	Requiring assessment	400	410
Paragraph 5(b)(ii)	Not requiring assessment	135	140
Paragraph 6	Wholesale dealer's licences		
Paragraph 6(a)	Variation requiring assessment	400	410
Paragraph 6(b)	Variation not requiring assessment	135	140
Paragraph 7	Variation of animal test certificate	220	225
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	335	345
Paragraph 1(c)	Other cases	1,000	1,025
Paragraph 2	Manufacturer's licences	100	105
Paragraph 3	Animal test certificates	100	105
SCHEDULE 2	**Fees relating to site inspections**		
Paragraph 2(1), Table A, column (2)			
entry 1	Supersite inspection	9,295	9,525
entry 2	Major inspection	4,890	5,010
entry 3	Standard inspection	3,500	3,590
entry 4	Minor inspection	1,890	1,935
Paragraph 2(2), Table B, column (2)			
entry 1	Supersite inspection	15,410	15,795
entry 2	Major inspection	8,515	8,730
entry 3	Standard inspection covering immunological Veterinary Medicinal Products	5,555	5,695
entry 4	Other standard inspection	4,185	4,290
entry 5	Minor inspection covering immunological Veterinary Medicinal Products	2,800	2,870
entry 6	Other minor inspection	2,800	2,870
Paragraph 2(3), Table C, column (2)			
entry 1	Supersite inspection	6,750	6,920
entry 2	Major inspection	4,560	4,675
entry 3	Standard inspection	2,235	2,290
entry 4	Minor inspection	1,155	1,185
Paragraph 2(4)(b)	Site limited solely to manufacture and assembly of emergency vaccines	105	110
Paragraph 3(1)	Either or both of premises and procedures for quality control of a biological product which is not a dormant product	1,335	1,370
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	115	120

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 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	335	345
entry 3	Any other application	560	575
Paragraph 1, Table, column (3)	Fees for applications in respect of products prepared from more than 5 homoeopathic stocks		
entry 1	Product both prepared soley from repeat stock and being of repeat formulation	275	280
entry 2	Product which is either prepared solely from repeat stock or is of a repeat formulation	495	505
entry 3	Any other application	720	740
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	115	120
Paragraph 2(ii)	Product prepared from more than 5 homoeopathic stocks	275	280
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	1,580	1,620
entry 2	Complex application	905	930
entry 3	Standard application	420	430
entry 4	Simple application	160	165
Paragraph 2	Animal test certificate	550	565

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.

Regulation 2 and the Schedule prescribe new fees in relation to the provisions specified there, with the previous fee shown as a comparison.

The average level of fees payable under these Regulations is increased by 2.5% in comparison with the 1998 Regulations as last amended.

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 that, for fees relating to turnover, the first relevant year is 2001.

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

2002 No. 2569

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