

SCHEDULE

Regulation 2

PART I

Column (1) <i>Provision in the principal Regulations</i>	Column (2) <i>Subject matter</i>	Column (3) <i>Old fee</i>	Column (4) <i>New fee</i>
		£	£
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

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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

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	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

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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 I 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

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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

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	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		

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	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

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Changes and effects yet to be applied to :

- Regulations revoked by [S.I. 2004/2750 reg. 18\(e\)](#)