DRAFT STATUTORY INSTRUMENTS

2024 No.

The Veterinary Medicines (Amendment etc.) Regulations 2024

PART 9

Amendments to Schedule 7 to the 2013 Regulations

Introduction

161. Schedule 7 to the 2013 Regulations (fees) is amended in accordance with this Part.

Amendment to paragraph 1

162. In paragraph 1 (interpretation)—

(a) the existing text is renumbered as sub-paragraph (1);

(b) in sub-paragraph (1), in the definition of "pharmaceutical product", at the end insert "or a biological veterinary medicinal product that is not immunological";

(c) after that sub-paragraph insert—

"(2) For the purposes of this Schedule "manufacturing authorisation" means the following activities—

(a) manufacture or import of an authorised veterinary medicinal product;

(b) manufacture of a product to which paragraph 2 of Schedule 6 relates;

(c) manufacture of a product for administration under the cascade;

(d) manufacture of—

(i) an autogenous vaccine;

(ii) a stem cell product; or

(iii) a blood product for administration to non-food animals.".

Amendment to paragraph 4

163. In paragraph 4 (multiple inspections)—

(a) omit ", approval";

(b) after "time," insert "and in relation to the same legal entity,".

Amendment to paragraph 7

164. In paragraph 7 (specified pharmaceutical applications)—

(a) after "a pharmaceutical" insert ", immunological or biological that is not immunological";

(b) in sub-paragraph (a)—

(i) at the end of paragraph (i) insert ", or";

(ii) in paragraph (ii)—

(aa) after "application" insert "for a pharmaceutical veterinary medicinal product";

(bb) omit "or";

(iii) omit paragraph (iii);

(c) in sub-paragraph (c) for the table substitute—

"Application	*Fee (£) per authorisation*
Base fee	27,995
Fee for 1st additional strength	4,590
Fee for each subsequent additional strength	1,465";

(d) in the heading, after "pharmaceutical" insert ", immunological or biological that is not immunological".

New paragraph 7A

165. After paragraph 7 insert—

"**Application for a marketing authorisation for specific applications**

7A. The fee for an application for a marketing authorisation which involves one or more of the following is £45,000—

(a) any biotechnical process involving recombinant DNA or the controlled expression of genes;

(b) a veterinary medicinal product containing a new active substance;

(c) a biopharmaceutical product.".

Amendment to paragraph 9

166. Omit paragraph 9 (application for marketing authorisation for immunological or biosimilar product).

Amendment to paragraph 11

167. For paragraph 11 (application for marketing authorisation based on informed consent) substitute—

"**Application for a marketing authorisation based on informed consent**

11. The fee for applications for marketing authorisations using identical data submitted simultaneously or on the basis of information provided under paragraph 9 of Schedule 1 is as follows—

Application	*Fee (£) per authorisation*
Application	1,465".

Amendment to paragraph 13

168. In paragraph 13 (application for exceptional marketing authorisation – immunological)—

(a) after "immunological product", in both places it occurs, insert "or a biological veterinary medicinal product that is not immunological";

(b) in the heading, for "(immunological)" substitute "(immunological or biological non-immunological)".

Amendment to paragraph 15

169. Omit paragraph 15 (application for marketing authorisation for parallel import).

New paragraph 15A

170. After paragraph 15 insert—

"**Fee for a generic marketing authorisation**

15A.—(1) The fee for a marketing authorisation in respect of a generic veterinary medicinal product is to be calculated in accordance with the following table.

Application	*Fee (£) per authorisation*	
	Hybrid	*Standard*
Base Fee	13,950	12,390
Fee for 1st additional strength	4,590	
Fee for each subsequent additional strength	1,465.	

(2) In this paragraph "hybrid" means an application to which paragraph 10A of Schedule 1 applies.".

Amendment to paragraph 17

171. In paragraph 17 (application for variation to marketing authorisation under national or mutual recognition procedure)—

(a) in sub-paragraph (1) omit "18, 19 or";

(b) for the table substitute—

"Type of variations	*Fee (£)*
Single variations; one change for each product **Variation – standard**	2,895
Unless the variation is—	
(a) a change of route of administration, or the addition of a new one, of—	
(i) an immunological product, or a pharmaceutical product for a non-food-producing animal	5,390
(ii) a pharmaceutical product for a food-producing animal	7,135
(b) a change of bioavailability	8,415
(c) a change of active substance, where the change is to—	

"Type of variations	*Fee (£)*
(i) use a different biologically active substance with a slightly different molecular structure	8,415
(ii) modify the vector used to produce the antigen or the source material, including a new master cell bank from a different source	8,415
(d) a change of pharmacokinetics	8,415
Simultaneous application falling within (a) to (d): fee for each additional product in the application	1,465
Variation – reduced	885
Variation - no assessment	455
Grouped variations	
Variation – standard led	
For the first nine changes	6,280
For each subsequent group of five or fewer changes	2,250
Variation – reduced led:	
For the first nine changes	1,770
For each subsequent group of five or fewer changes	2,250".

Amendment to paragraph 18

172. Omit paragraph 18 (application for variation to marketing authorisation under worksharing procedure).

Amendment to paragraph 22

173. In paragraph 22 (application for renewal of marketing authorisation)—

(a) omit sub-paragraph (1);

(b) for the heading substitute—

"Application for a reassessment of an exceptional marketing authorisation".

Amendment to paragraph 25

174. Omit paragraph 25 (renewal of homeopathic remedy).

Amendment to paragraph 28

175. In paragraph 28 (application for manufacturing authorisation)—

(a) the existing text is renumbered as sub-paragraph (1);

(b) for the words from "is—" to the end substitute "is £762";

(c) after sub-paragraph (1) insert—

"(2) Fees relating to an application for a manufacturing authorisation are payable with the application.".

Amendment to paragraph 29

176. In paragraph 29 (application for variation to manufacturing authorisation)—

(a) in sub-paragraph (a) for "£636" substitute "£684";

(b) for sub-paragraph (b) substitute—

"(b) £105 if the variation only involves an administrative variation such as a change of ownership.";"

(c) omit sub-paragraphs (c) and (d).

Amendment to paragraph 30

177. In paragraph 30 (application for manufacturing authorisation for autogenous vaccine or product for administration under the cascade)—

(a) omit sub-paragraph (1);

(b) for sub-paragraph (2) substitute—

"(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) for the manufacture of unauthorised veterinary medicinal products for administration under the cascade are set out in the following table—

Inspection fees

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the United Kingdom
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577".

(c) omit sub-paragraphs (3) and (4);

(d) for the heading substitute—

"Inspection of sites authorised to manufacture a product for administration under the cascade".

New paragraphs 30A and 30B

178. After paragraph 30 insert—

"**Autogenous vaccines**

30A.—(1) The fee for the scientific assessment of an authorisation (or an application for authorisation) to manufacture an autogenous vaccine is £6,962.

(2) The fees for the inspection of sites in connection with an authorisation (or an application for authorisation) to manufacture autogenous vaccines are set out in the following table—

Inspection fees

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the United Kingdom
Super site	21,416	22,710
Major site	12,850	14,144
Standard site	6,425	7,719
Minor site	4,283	5,577

Assessment of a variation of an authorisation to manufacture an autogenous vaccine

30B. The fee for the scientific assessment of an application for the variation of an authorisation to manufacture an autogenous vaccine is—

(a) £2,895 if the variation requires complex scientific or pharmaceutical assessment;

(b) £885 if the variation requires simple scientific or pharmaceutical assessment;

(c) £455 in relation to an administrative variation.".

Amendment to paragraph 31

179. For paragraph 31 (annual fees) substitute—

"**Annual fee (manufacturing authorisations)**

31. An annual fee of £575 is payable in respect of each manufacturing authorisation held.".

Amendment to paragraph 33

180. In paragraph 33 (inspection of manufacturing site for immunological veterinary medicinal products) for the table substitute—

"**Sites where immunological veterinary medicinal products are manufactured**

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the United Kingdom
Super site	32,124	33,418
Major site	21,416	22,710
Standard site	10,708	12,002
Minor site	6,425	7,719".

Amendment to paragraph 34

181. In paragraph 34 (inspection of manufacturing site for sterile veterinary medicinal products) for the table substitute—

"**Sites where sterile veterinary medicinal products are manufactured**

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the United Kingdom
Super site	27,841	29,135
Major site	19,274	20,569
Standard site	10,708	12,002
Minor site	6,425	7,719".

Amendment to paragraph 35

182. In paragraph 35 (inspection of manufacturing site for other veterinary medicinal products) for the table substitute—

"**Sites where no immunological or sterile veterinary medicinal products are manufactured**

Type of site		*Fee (£)*	
		United Kingdom site	Site outside the United Kingdom
Super site		21,416	22,710
Major site		12,850	14,144
Standard site		8,566	9,861
Minor site		4,283	5,577
If the site is only involved in the manufacture of veterinary medicinal products authorised under Schedule 6 (exemptions for small pet animals) —			
	Standard site	3,212	4,507
	Minor site	2,142	3,436".

Amendment to paragraph 36

183. In paragraph 36 (inspection of site where veterinary medicinal products are assembled) for the table substitute—

"**Sites where medicinal products are assembled**

Type of site	*Fee (£)*	
	United Kingdom site	Site outside the United Kingdom
Super site	17,133	18,427
Major site	10,708	12,002
Standard site	6,425	7,719

Type of site		*Fee (£)*
Minor site	4,283	5,577".

Amendment to paragraph 37

184. In paragraph 37 (test sites)—

(a) for "£3,344" substitute "£3,212";

(b) for "£3,177" substitute "£4,507".

Amendment to paragraph 38

185. For paragraph 38 (animal blood bank or equine stem cell centre authorisations) substitute—

"**Animal blood bank or non-food animal stem cell centre authorisations**

38.—(1) The fee for the inspection of a blood bank is—

(a) £3,212 for a site in the United Kingdom; and

(b) £4,507 for a site outside the United Kingdom.

(2) The fee for the inspection of a non-food animal stem cell centre is—

(a) £2,142 for a site in the United Kingdom; and

(b) £3,436 for a site outside the United Kingdom".

Amendment to paragraph 39

186. For paragraph 39 (application for wholesale dealer's authorisation) substitute—

"**Application for a wholesale dealer's authorisation**

39.—(1) The fee for an application for a wholesale dealer's authorisation is £344.

(2) Fees relating to an application for a wholesale dealer's authorisation are payable with the application.".

Amendment to paragraph 40

187. For paragraph 40 (variation of wholesale dealer's authorisation) substitute—

"**Variation of a wholesale dealer's authorisation**

40. The fee for an application to vary a wholesale dealer's authorisation is—

(a) £265 if the variation requires scientific or pharmaceutical assessment;

(b) £105 for a change of ownership or other administrative variation.".

Amendment to paragraph 41

188. For paragraph 41 (annual fee for wholesale dealer's authorisation) substitute—

"**Annual fee for a wholesale dealer's authorisation**

41. The annual fee for a wholesale dealer's authorisation is £427.".

Amendment to paragraph 42

189. For paragraph 42 (inspection of wholesale dealer's premises) substitute—

"**Inspection of a wholesale dealer's sites**

42. The fee for inspection of a wholesale dealer's site is—

(a) £1,177; or

(b) £877 if—

(i) the authorisation only relates to products classified as AVM-GSL or homeopathic remedies; or

(ii) the authorisation only relates to products marketed under Schedule 6 (exemptions for small pet animals).".

Amendment to paragraph 43

190. In paragraph 43 (approval fees and annual fees for feedingstuffs in Great Britain)—

(a) in sub-paragraph (1)—

(i) for "approval", in both places it occurs, substitute "authorisation";

(ii) for "establishments" substitute "premises";

(iii) for "£70" substitute "£105";

(b) in sub-paragraph (2)—

(i) for "£70" substitute "£122";

(ii) for "approval" substitute "authorisation";

(c) in sub-paragraph (3)—

(i) for "an establishment" substitute "premises";

(ii) for "veterinary medicinal product intended to be incorporated into feedingstuffs" substitute "medicinal premix";

(iii) for "that establishment" substitute "those premises";

(d) in sub-paragraph (4) omit "or on invoice for the subsequent annual fee";

(e) in sub-paragraph (5) for "establishment" substitute "premises by the same legal entity";

(f) in the heading for "approvals" substitute "applications for authorisation".

Amendment to paragraph 44

191. In paragraph 44 (inspection fees for feedingstuffs in Great Britain)—

(a) in the words before the table for "establishments" substitute "premises";

(b) for the table substitute—

"**Inspection Fees**

Type of premises inspected	*Fee payable (£)*
Manufacturer of a specified feed additive (SFA)	1,610
Manufacturer of an intermediate feedingstuff (including balancers) containing a medicinal premix or an SFA	976
Manufacturer of a feedingstuff for sale containing—	841

Type of premises inspected	*Fee payable (£)*
a medicinal premix and/or an SFA, and/or an intermediate feedingstuff containing a medicinal premix or an SFA	
Manufacturer of a feedingstuff for feeding to their own animals only, containing— a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t, and/or an intermediate feedingstuff containing a medicinal premix and/or an SFA incorporated at a rate of at least 2kg/t	476
Distributor or trader of Schedule 5 products (A distributor of specified feed additives, or intermediate feedingstuffs containing specified feed additives or medicinal premixes; or feedingstuffs containing a medicinal premix)	350”.

Amendment to paragraph 46

192. In paragraph 46 (premises for supply by suitably qualified persons)—

(a) in sub-paragraph (1)—

(i) for “to approve” substitute “for an application for the authorisation”;

(ii) for “£265” substitute “£105”;

(iii) omit paragraph (b) and the preceding “or”;

(b) after sub-paragraph (1) insert—

“(1A) The fees for the inspection of sites authorised for the retail supply of veterinary medicinal products by suitably qualified persons are set out in the following table—

Inspection Fees

Type of sites inspected	*Fee payable (£)*
Sites authorised to supply companion animal medicines	285
Sites authorised to supply equine medicines	285
Sites authorised to supply livestock medicines	338
Sites authorised to supply avian medicines	285.

(1B) Where a site is inspected in relation to a single authorisation, and falls within more than one of the categories in the table, only one fee (the highest) is payable.”;

(c) in sub-paragraph (2)—

(i) for “£185” substitute “£57”;

(ii) omit paragraph (b) and the preceding “or”;

(d) after sub-paragraph (2) insert—

"(3) The application fee for authorisation of sites for supply is payable with the application.".

Amendment to paragraph 48

193. In paragraph 48 (animal test certificates)—

(a) in sub-paragraph (1) for "£815" substitute "£1,170";

(b) in sub-paragraph (2) for "£30" substitute "£40";

(c) for sub-paragraph (4) substitute—

"(4) The fee for an application for the variation of the certificate is—

(a) in the case of a small scale trial, £40; and

(b) in the case of any other trial, £390.";

(d) for sub-paragraph (5) substitute—

"(5) The fee for an application to renew a certificate is—

(a) in the case of a small scale trial, £40; and

(b) in the case of any other trial, £190.".

Amendment to paragraph 53

194. In paragraph 53 (export certificates)—

(a) for "£30" substitute "£54";

(b) omit the words from ", and £15" to the end.

New paragraph 54A

195. After paragraph 54 (provision of advice) insert—

"**Provision of scientific advice**

54A. The fee for an application for written advice from the Secretary of State in relation to scientific matters is £4,487.".

Amendment to paragraph 57

196. In paragraph 57 (veterinary surgeon's practice premises)—

(a) for sub-paragraph (1) substitute—

"(1) The fees for the inspection of a veterinary practice premises are set out in the following table—

Type of premises inspected	*Fee payable (£)*
Sites registered to supply companion animal medicines	536
Sites registered to supply equine medicines	536
Sites registered to supply livestock medicines	536
Mixed practice premises	698
Any other type of practice	451".

(b) in sub-paragraph (2), for "£34" substitute "£38";

(c) after sub-paragraph (3) insert—

"(4) For the purposes of sub-paragraph (1) "mixed practice" means premises supplying veterinary medicinal products to livestock in addition to any other category mentioned in that provision.";

(d) in the heading omit "surgeon's".

New paragraphs 57A and 57B

197. After paragraph 57 insert—

"**Fee in relation to verifying destruction of controlled drug**

57A. The fee for verifying the destruction of a controlled drug listed in Schedule 2, 3 or 4 to the Misuse of Drugs Regulations 2001(**1**) is—

(a) £142; or

(b) £31 (where the verification takes place during the course of an inspection for other purposes).

Pharmacovigilance inspections

57B.—(1) In relation to a pharmacovigilance inspection the fee is—

(a) £3,600 in the case of a large marketing authorisation holder; and

(b) £1,650 in the case of a small marketing authorisation holder.

(2) In sub-paragraph (1)—

"large marketing authorisation holder" means a marketing authorisation holder who holds 30 or more marketing authorisations;

"small marketing authorisation holder" means a marketing authorisation holder who holds fewer than 30 marketing authorisations.".

Amendment to paragraph 60

198. In paragraph 60 (non-payment of fees)—

(a) omit "(other than any fee relating to a manufacturing authorisation or wholesale dealer's authorisation)";

(b) after "from the person" insert "or any authorisation held by the person".

Amendment to paragraph 61

199. After paragraph 61(1) (waiver or reduction of fees) insert—

"(1A) If the Secretary of State is satisfied that exceptional circumstances exist the Secretary of State may waive or reduce an inspection fee payable under these Regulations.".

(**1**) S.I. 2001/3998, amended by S.I. 2003/1432, 2005/3372, 2007/2154, 2009/3136, 2011/448, 2012/973, 1311, 2013/625, 2014/1275, 3277, 2015/891, 2016/1125, 2018/1055, 1383; there are other amending instruments but none is relevant.