SCHEDULE 7

FEES

PART 2

Fees relating to marketing authorisations

Application for a variation

13.—(1) An applicant must make a separate application for a variation for each change in the marketing authorisation (unless a change is a direct consequence of the first change) and the appropriate fee is payable for each application.

(2) As an exception from sub-paragraph (1), if an applicant applies for more than one variation to the quality data in a marketing authorisation on the same application form, he may elect to pay a total fee of £4,440; but this sub-paragraph does not apply—

(a) if one or more of the variations relates to a new source of an active substance and the applicant does not submit a Certificate of Suitability issued by the European Pharmacopeia relating to the new source, or

(b) if a significant formulation change is applied for that requires a new assessment of the safety or efficacy of the veterinary medicinal product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £440 for a variation specified as Type 1A in that Annex.

(4) If the variation is specified as Type 1B in that Annex, the fee is £835 except in accordance with the following table.

Reductions to Type 1B fees

Variation	*Conditions*	*Fee (£)*
Identical changes to a number of products—	All the products are from the same marketing authorisation holder Supporting data are identical All applications are submitted at the same time	First product 835 Each subsequent product 440

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No.1084/2003 is £2,220 except in the following cases, where the fee is as specified.

Reductions to Type II fees

Change	*Conditions*	*Fee (£)*
(a) (a) Identical changes to a number of products—	All the products are from the same marketing authorisation holder Supporting data are identical	First product 2,220 Each subsequent product 440

Change	*Conditions*	*Fee (£)*
	All applications are submitted at the same time	
(b) (b) Change of distributor—	No other aspect of the dossier is changed and the marketing authorisation holder remains the same	835
(c) (c) Change of legal entity of marketing authorisation holder—	No other aspect of the dossier is changed	835
(d) (d) Simple dosage instruction changes intended to remove ambiguity—	The change is not as a result of safety concerns No new studies are required to support the change The dosage regime remains the same	835
(e) (e) Addition or change to safety warnings—	No other aspects of the dossier are changed No 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/ environment/target species as appropriate	835
(f) (f) Corrections or simple text layout changes to summary of product characteristics and/or product literature. Included in this is the introduction of multilingual labelling—	The changes are not a result of safety concerns No new studies are required to support the change and no other aspect of the dossier is changed The legibility of the current English labelling is not compromised The indications and warnings are the same in all languages	835
(g) (g) Abbreviated resubmission of a previously refused Type II variation—	At the time of refusal of a Type II variation, the Secretary of State has given written permission for resubmission under this category	835

Change	*Conditions*	*Fee (£)*
	The application has been resubmitted within 3 months of the date the refusal advice was issued	
(h) (h) Submission made following the formal advice of the Secretary of State—	The Secretary of State has already assessed the relevant data and formed an opinion on these The change is not required as a result of the holder failing to keep the Part II (quality) data in accordance with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**1**)	835
(i) (i) Approval of a mock-up for an authorised pack size—	The pack size is already authorised No new studies are required to support the change and no other aspect of the dossier is changed	835
(j) (j) Changes to the summary of product characteristics and product literature of a Marketing Authorisation for Parallel Import as a direct consequence of the approval of a variation to the summary of product characteristics and product literature for the United Kingdom authorised product—	The only changes to the summary of product characteristics and product literature are those required to bring the marketing authorisation for parallel import back in direct line with those of the United Kingdom authorised product	835

Commencement Information

I1 Sch. 7 para. 13 in force at 1.10.2006, see **reg. 1**

(**1**) The Committee was established by Article 30 of Regulation (EC) No. 762/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ No. L 136, 30.4.2004, p. 1.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2006, Paragraph 13.