SCHEDULE 7

Fees

PART 2

Fees relating to national marketing authorisations

Scope of Part 2

4. This Part has effect in relation to marketing authorisations which are confined to the United Kingdom and where there is not, or has not been, an application using the decentralised or mutual recognition procedures.

Standard application for a marketing authorisation

5. The fee for an application (referred to in this Schedule as a "standard application") for a marketing authorisation that does not fall into any of the following categories in this Part is £6,390.

Application for a marketing authorisation for a product with an active substance not contained in a veterinary medicinal product previously authorised in the United Kingdom

6.—(1) The fee for an application for a marketing authorisation for a veterinary medicinal product that contains an active substance which has not previously been included in an authorised veterinary medicinal product in the United Kingdom is £25,500.

(2) This is referred to in this Schedule as an "application for a new active substance".

(3) If additional applications are submitted at the same time for different strengths of the same active substance in the same dosage form, the fee for each additional strength is £6,390.

(4) If an additional application is submitted at the same time for another dosage form the fee for that additional dosage form is £14,795 and the fee for additional applications for the same dosage form is £ 6,390.

(5) The fee for immunological products submitted at the same time with lesser combination of antigens is £6,390 for each application.

Application for a marketing authorisation involving other aspects not previously authorised in a veterinary medicinal product in the UK

7.—(1) The fee for an application for a marketing authorisation where all the active substances of the veterinary medicinal product have previously been included in a veterinary medicinal product authorised in the United Kingdom but which has an element within the application and supporting data that has not previously been successfully assessed in relation to any of the active substances is £14,795.

(2) This is referred to in this Schedule as a "complex application".

(3) Examples of applications covered by sub-paragraph (1) are the following relating to any of the active substances—

(a) a different target species;

(b) a different indication for the target species;

(c) a different route of administration;

(d) a different adjuvant or excipient;

(e) a different method of sterilisation, synthesis or manufacture;

(f) the product has a controlled release preparation which is new for that active substance;

(g) in the case of an immunological product, the product uses a different growth medium;

(h) the active substance in the product is manufactured by a different manufacturer;

(i) the active substance is in a different dosage form.

(4) If additional applications are submitted at the same time for different strengths of the same active ingredient in the same dosage form, the fee for each additional strength is £6,390.

Pharmacologically equivalent products

8.—(1) The fee for an application for a marketing authorisation for a product that is pharmacologically equivalent to a product authorised in the United Kingdom is £4,995.

(2) This is referred to in this Schedule as an "application for a pharmacologically equivalent product".

(3) The fee for such an application where the reference product is authorised within the European Union but not within the United Kingdom is £6,390 plus any translation costs.

Application for a marketing authorisation using identical data

9. The fee for an application for a marketing authorisation that uses existing data relating to an authorised product and where the new product is identical in all respects (other than the name) to an existing product (referred to in this Schedule as an "application using identical data") is £1,785.

Application for a provisional marketing authorisation

10.—(1) The fee for an application for a provisional marketing authorisation for a new active substance is £14,795, and the fee for its conversion into a full marketing authorisation is—

(a) £10,705 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or

(b) in any other case £25,500.

(2) The fee for a complex application for a provisional marketing authorisation is £6,390, and the fee for its conversion into a full marketing authorisation is—

(a) £8,405 if the application for the full marketing authorisation is received within two years of the grant of the provisional marketing authorisation, or

(b) in any other case £14,795.

Application for a marketing authorisation relating to a parallel import

11.—(1) The fee for a marketing authorisation for a product imported in accordance with paragraph 13 of Schedule 1 (parallel imports) is £2000 for each member State from which a product is to be imported plus any translation costs.

(2) If the imported product has been authorised in accordance with the Mutual Recognition Procedure or Decentralised Procedure, and the United Kingdom is included within these procedures, the fee is £1650 for one member State on the application plus £330 for each additional member State on the application.

Application for a variation

12.—(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) The fee for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003 is the same as the fee for an application for a marketing authorisation for that product.

(3) If the variation is one specified in Annex I to Commission Regulation (EC) No. 1084/2003, the fee is £330 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 £770 except in the following case—

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	The fee for the first product is £770 and the fee for each subsequent product is £330

(5) The fee for a variation classified as Type II in Article 3 of Commission Regulation (EC) No. 1084/2003 is £2,540 except in the following cases, where the fee is as specified:

Reductions to Type II fees

Change	*Conditions*	*Fee*
a) 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	The fee for the first product is £2540, and the fee for each subsequent product is £330
b) Change of Distributor.	– No other aspect of the dossier is changed and the marketing authorisation holder remains the same.	£770
c) Change of legal entity of marketing authorisation holder.	– No other aspect of the dossier is changed.	£770
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.	£770

Change	*Conditions*	*Fee*
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.	£770
f) Corrections or simple text lay out 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	£770
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. — The application has been resubmitted within 3 months of the date the refusal advice was issued	£770
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 accord with current practice or in line with current guidelines issued by the Committee for Medicinal Products for Veterinary Use(**1**).	£770
i) Approval of a mock-up for an authorised pack size.	— The pack size is already authorised.	£770

(**1**) The Committee was established by Article 30 of Regulation (EC) No. 726/2004 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. L136, 30.4.2004, p. 1.

Change	*Conditions*	*Fee*
	— No new studies are required to support the change and no other aspect of the dossier is changed.	
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 UK 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 UK authorised product.	£770

Application for the renewal of a marketing authorisation

13.—(1) The fee for the renewal of a marketing authorisation issued after these Regulations come into force is £1,275.

(2) In the case of a marketing authorisation issued before these Regulations come into force—

(a) if it is the first time the marketing authorisation has been renewed the fee is £1,275; and otherwise £290;

(b) if further assessment of post authorisation commitments is required the fee is £1,275.

(3) The fee for the first reassessment of a provisional marketing authorisation is £290, and the fee for each subsequent reassessment is £1,275.

Registration of a homoeopathic veterinary medicinal product

14. The fee for an application for the registration of a homoeopathic veterinary medicinal product is in accordance with the following table:

Fee for the registration of a homoeopathic veterinary medicinal product

Type of application	*Fee(£)*
If all stocks and the formulation have already been assessed by the Secretary of State—	
– not more than 5 stocks	150
– more than 5 stocks	350
If either all the stocks have already been assessed by the Secretary of State but there is a new formulation, or if the formulation has already been assessed by the Secretary of State but one or more of the stocks have not been already assessed—	
– not more than 5 stocks	430
– more than 5 stocks	625

Type of application	*Fee(£)*
If the formulation and at least one of the stocks has not already been assessed by the Secretary of State—	
– not more than 5 stocks	710
– more than 5 stocks	920
If the product is already authorised for human use in the United Kingdom, or for human or veterinary use in the United Kingdom or in another member State—	
– not more than five stocks	150
– more than five stocks	350