SCHEDULE 7

Fees

PART 3

Fees relating to decentralised and mutual recognition procedures

Scope of Part 3

15. This Part has effect in relation to marketing authorisations applied for or obtained using the decentralised procedure or the mutual recognition procedure.

Provision of information relating to the recognition of United Kingdom marketing authorisation

16.—(1) Where an application is made for the Secretary of State to provide information to other member States to enable them to recognise a marketing authorisation already granted by the United Kingdom the following fees are payable.

(2) Where the application to provide information to another member State is received within six months of the original grant of the marketing authorisation, or where the Secretary of State has already provided the information to a member State, and a further application is made for her to provide the information to an additional member State within six months of the date she last provided the information—

(a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £2,290;

(b) if the product is an immunological veterinary medicinal product the fee is £2,000;

(c) in any other case the fee is £1,775.

(3) In any other case —

(a) if the product is not an immunological veterinary medicinal product and one of the target species is a food-producing animal the fee is £9,860;

(b) if the product is an immunological veterinary medicinal product the fee is £8,385;

(c) in any other case the fee is £6,905.

(4) The fees include the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

Mutual recognition of a marketing authorisation already granted in another member State

17.—(1) A fee for the recognition by the Secretary of State of a marketing authorisation already granted in another member State is as follows—

Fee for mutual recognition

Type of application	*Fee(£)*
Standard application	4,225
Application for a new active substance	14,070
Complex application	8,445

Type of application	*Fee(£)*
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	3,305
Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom	4,225 plus any translation costs
Application using identical data	1,120

Decentralised procedure where the United Kingdom is the reference member State

18.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is the reference member State—

Fee for the decentralised procedure where the United Kingdom is the reference member State

Type of application	*Fee(£)*
Standard application	10,400
Application for a new active substance	29,510
Complex application	18,800
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	9,000
Application for a pharmacologically equivalent product where reference product is not authorised in the United Kingdom	10,400 plus any translation costs
Application using identical data	4,075

(2) In each case the fee includes the provision of information to one member State in the application; there is a further fee of £500 for each additional member State included in the application.

Decentralised procedure where the United Kingdom is not the reference member State

19.—(1) Where an application is submitted using the decentralised procedure the following fees are payable if the United Kingdom is not the reference member State—

Fee for the decentralised procedure where the United Kingdom is not the reference member State

Type of application	*Fee(£)*
Standard application	4,225
Application for a new active substance	14,070
Complex application	8,445
Application for a pharmacologically equivalent product where the reference product is authorised in the United Kingdom	3,305

Type of application	*Fee(£)*
Application for a pharmacologically equivalent product where the reference product is not authorised in the United Kingdom	4,225 plus any translation costs
Application using identical data	1,680

Application for a variation

20.—(1) In this paragraph the types of variation are those specified in Commission Regulation (EC) 1084/2003.

(2) 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.

(3) If an applicant applies for an extension of a marketing authorisation as specified in Annex II to Commission Regulation (EC) No. 1084/2003—

(a) if the applicant applies for a United Kingdom marketing authorisation the fee is the same as the fee for the application for a national marketing authorisation, plus any fees payable for any mutual recognition procedure; or

(b) if the applicant uses the decentralised procedure, the fee is the same as the fee for a marketing authorisation using the decentralised procedure.

(4) Other fees are in accordance with the following table—

Variations

Type of variation	*RMS Fee(£)*	*CMS Fee(£)*
Type II variation	10,125	2,540
If a marketing authorisation holder applies for a Type II variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time the fee payable is		
— for the first variation	10,125	2,540
— for each subsequent variation	1,675	330
If a marketing authorisation holder— — applies for a Type II variation to correct the Summary of Product Characteristics or product literature or where variations		

Type of variation	*RMS Fee(£)*	*CMS Fee(£)*
are required for simple text lay out changes — the change is not a result of safety concerns — no new studies are required to support the change — no other aspects of the dossier are changed.		
the fee payable is	2,705	355
Type 1A variation	1,675	330
Type 1B variation	2,705	355
If a marketing authorisation holder applies for a Type 1B variation for a number of marketing authorisations, and— — all the applications have identical supporting data — all the changes are identical — all the applications are submitted at the same time		
the fee payable is		
— for the first variation	2,705	355
— for each subsequent variation	1,675	330

Note: the RMS fee is payable when the United Kingdom acts as the reference member State and the CMS fee is payable when the United Kingdom acts as the concerned member State.

Application for the renewal of a marketing authorisation

21.—(1) The fee for the renewal of a marketing authorisation granted in more than one member State is —

(a) £1,720 if the United Kingdom is the reference member State, and

(b) £1,145 where the United Kingdom is a concerned member State.