SCHEDULE 5

Regulation 14

FEES RELATING TO APPLICATIONS FOR REGISTRATION OF HOMOEOPATHIC VETERINARY MEDICINAL PRODUCTS

PART I

INTERPRETATION

In this Schedule–

"application" means an application to register a product;

"formulation" means the formulation of a product but does not include the formulation of a homoeopathic stock contained in such a product;

"the Homoeopathics Directive" means Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homoeopathic veterinary medicinal products(**1**) as adapted by the EEA Agreement;

"homoeopathic stock" has the same meaning as in the Homoeopathics Directive;

"identical" means–

(a) in relation to the formulation of a product, identical as regards the requirements in respect of the qualitative composition, preparation and testing;

(b) in relation to a homoeopathic stock, identical as regards the source, composition and preparation of the stock and the tests which it is required to undergo;

"product" includes a series of products which are all dilutions prepared from an identical homoeopathic stock or stocks and each of which has the same pharmaceutical dosage form;

"repeat formulation", in relation to an application, means–

(a) the formulation of a product which is identical to the formulation of a registered product–

(i) which the applicant is responsible for marketing; or

(ii) to which the applicant has been authorised in writing to make reference for the purposes of his application by the person responsible for marketing that product; or

(b) the formulation of a product which is identical to another product in respect of which the applicant has made a simultaneous application;

"repeat stock", in relation to an application, means–

(a) a homoeopathic stock which is used in the preparation of a product (either on its own or in combination with another homoeopathic stock or stocks), and which is identical to another homoeopathic stock which is used (whether on its own or in combination with any other homoeopathic stock or stocks) in the preparation of a registered product–

(i) which the applicant is responsible for marketing; or

(ii) which another person is responsible for marketing and to which the applicant has been authorised in writing to make reference for the purposes of the application by the person (or, if more than one, each of such persons) who supplied information to the Ministers in connection with the application made to register that registered product; or

(**1**) OJNo. L297, 13.10.92, p.12.

(b) a homoeopathic stock which is used in the preparation of a product (either on its own or in combination with another homoeopathic stock or stocks), and which is identical to a homoeopathic stock which is used (whether on its own or in combination with any other homoeopathic stock or stocks) in the preparation of a product in respect of which the applicant has made a simultaneous application; and

"simultaneous application" means an application which is made by an applicant at the same time as making another application or applications, and which is the first of such applications to be considered by the Ministers.

PART II

FEES RELATING TO APPLICATIONS FOR REGISTRATION

1. Subject to paragraph 2, the fee for an application of a kind described in an entry in column (1) of the Table below shall be–

(a) the fee specified in the corresponding entry in column (2) of that Table in the case of a product prepared from not more than 5 homoeopathic stocks; and

(b) the fee specified in the corresponding entry of column (3) of that Table in the case of a product prepared from more than 5 homoeopathic stocks.

Table

Column (1) *Description of application*	*Column (2)* *Fees for applications in respect of products prepared from not more than 5 homoeopathic stocks*	*Column (3)* *Fees for applications in respect of products prepared from more than 5 homoeopathic stocks*
An application in respect of a product which is both prepared solely from a repeat stock or stocks and is of a repeat formulation	£100	£250
An application in respect of a product which is either– (a) prepared solely from a repeat stock or stocks; or (b) is of a repeat formulation	£300	£450
Any other application	£500	£650

2. Where an application for registration relates to a product–

(a) for which a certificate of registration has been granted in relation to a product which is equivalent to it under Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**2**); or

(**2**) S.I.1994/105, amended by S.I. 1994/899, 1995/541, 1996/482.

(b) which is registered or authorised in an EEA State under legislation which implements the provisions of Article 6 of the Homoeopathics Directive in such State,

the fee for such application shall be–

(i) £100 in the case of a product prepared from not more than 5 homoeopathic stocks, and

(ii) £250 in the case of a product prepared from more than 5 homoeopathic stocks.

PART III

WAIVER OR REFUND OF FEES

1. Subject to paragraph 2, where an application for registration is withdrawn before determination by the Ministers, the following percentage of the fee otherwise payable in connection with that application shall be refunded or, if it has not yet been paid, shall be waived–

(a) if the application has been received but no veterinary, scientific or pharmaceutical assessment thereof has begun, 90%; and

(b) if veterinary, scientific or pharmaceutical assessment has begun but has not been completed, 50%.

2. If an application for registration is withdrawn either after veterinary, scientific or pharmaceutical assessment has been completed, or following consideration of that application by the Board or by the Medicines Commission, no refund or waiver of the fee payable in connection with that application shall be made.