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STATUTORY INSTRUMENTS

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**1996 No. 482**

**The Medicines (Homoeopathic Medicinal Products  
for Human Use) Amendment Regulations 1996**

**Substitution of Schedule 2 to the principal Regulations**

**3.** For Schedule 2 to the principal Regulations (fees for applications for the grant of certificates of registration) there is substituted the following Schedule—

“SCHEDULE 2

Regulation 13

FEEES FOR APPLICATIONS FOR THE GRANT OF CERTIFICATES OF REGISTRATION

**1.** In respect of an application which relates to a product prepared from not more than 5 homoeopathic stocks, the fee shall be the amount set out in Column (2) in the Table below opposite the description in Column (1) appropriate to the application.

**2.** In respect of any other application, the fee shall be the amount set out in Column (3) in the Table below opposite the description in Column (1) appropriate to the application.

**3.** In this Schedule—

“application” means an application for the grant of a certificate of registration;

“formulation” does not include the formulation of a homoeopathic stock;

“identical” means—

(a) in relation to the formulation of a product, identical as regards the requirements in respect of 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 each of which is prepared from identical homoeopathic stocks;

“repeat formulation” means—

(a) the formulation of a product which is identical to the formulation of another product—

(i) in respect of which the applicant holds a certificate of registration; or

(ii) to which the applicant has, by the holder of the certificate of registration which relates to it, been authorised in writing to make reference for the purposes of his application; or

(b) where more than one application is made by the same applicant on the same occasion in respect of products of identical formulations, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the formulation of the product to which the first of those applications which is considered by the licensing authority relates;

“repeat stock” means—

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*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

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- (a) a homoeopathic stock which is identical to another homoeopathic stock which is used in the preparation of a product—
- (i) in respect of which the applicant holds a certificate of registration; or
  - (ii) in respect of which another person holds a certificate of registration to which, for the purposes of his application, the applicant has been authorised in writing to make reference by the person (or, if more than one, each of the persons) who supplied information to the licensing authority in connection with the application for the certificate of registration which relates to that product; or
- (b) where more than one application is made by the same applicant on the same occasion in respect of products prepared from identical homoeopathic stocks, for the purposes of the second and any subsequent of those applications which the licensing authority considers, the homoeopathic stock used in the preparation of the product to which the first of those applications which is considered by the licensing authority relates.

TABLE

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