STATUTORY INSTRUMENTS

1996 No. 482

MEDICINES

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

Made - - - -	*29th February 1996*
Laid before Parliament	*1st March 1996*
Coming into force - -	*1st April 1996*

The Secretary of State, in exercise of powers conferred on him by section 2(2) of the European Communities Act 1972(**1**), being designated for the purposes of that section in relation to medicinal products(**2**), hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1996 and shall come into force on 1st April 1996.

(2) In these Regulations, "the principal Regulations" means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**3**).

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and interpretation), after paragraph (3) there is added the following paragraph—

"(4) In Schedule 2, paragraph 3 (interpretation) shall have effect for the purposes of that Schedule.".

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—

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) S.I. 1994/105; the relevant amending instrument is S.I. 1995/541.

"SCHEDULE 2 Regulation 13

FEES 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—

(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

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 other applications*
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— (a) prepared solely from repeat stocks; or (b) is of a repeat formulation	£300	£450
3. Any other application	£500	£650”

Amendment of Schedule 4 to the principal Regulations

4. In Schedule 4 to the principal Regulations (application of provisions of the Act), in the second entry in Column (2) which is opposite the entry “section 21” in Column (1), for the words “regulation 5(2) of” in both places where they occur there is substituted “regulation 5(4) of”(**4**).

Stephen Dorrell
One of Her Majesty’s Principal Secretaries of State,
Department of Health

29th February 1996

(**4**) Regulation 5(4) was substituted by regulation 2 of S.I. 1995/541.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the principal Regulations"). The principal Regulations implemented in part Council Directive 92/73/EEC (OJ L297 13.10.92, p. 8) by introducing a simplified registration procedure for the marketing of certain homoeopathic medicinal products for human use.

Regulation 3 makes new provision for the fees payable under Part III of the principal Regulations in respect of applications for certificates of registration. For Schedule 2 to the principal Regulations (which prescribed a fee of £335 where a certificate of registration had previously been granted and a fee of £475 in other cases) there is substituted a new Schedule. The fees prescribed in the new Schedule (which range from £100 to £650) are determined by the number of homoeopathic stocks used in the preparation of homoeopathic medicinal products and by criteria relating to whether the licensing authority has previously assessed stocks and formulations identical to those proposed to be used.

Regulation 4 corrects a reference in Schedule 4 to the principal Regulations.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament and further copies of which may be obtained from the Medicines Control Agency, Department of Health, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.