STATUTORY INSTRUMENTS

1995 No. 541

MEDICINES

The Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1995

Made - - - -	*3rd March 1995*
Laid before Parliament	*9th March 1995*
Coming into force - -	*1st April 1995*

The Secretary of State, in exercise of powers conferred on her 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 1995 and shall come into force on 1st April 1995.

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

Amendment of regulation 5 of the principal Regulations

2. For paragraph (4) of regulation 5 (determination of application for certificate) there shall be substituted—

> "(4) The licensing authority shall consult the Board before refusing to grant a certificate of registration on the ground set out in paragraph (2)(d) above, or, except in the case of a product to which paragraph (3) above applies, on the ground set out in paragraph (2)(c) above.".

Amendment of regulation 14 of the principal Regulations

3. In regulation 14 of the principal Regulations (fees for variations of certificates), for "£90" there shall be substitued "£85".

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) S.I. 1994/105, amended by S.I. 1994/899.

Amendment of Schedule 2 to the principal Regulations

4. In Schedule 2 to the principal Regulations (fees for applications for the grant of certificates)—

(a) in paragraph 1, for "£500" there shall be substituted "£475"; and

(b) in paragraph 2, for "£350" there shall be substituted "£335".

Virginia Bottomley
One of Her Majesty's Principal Secretaries of State,
Department of Health

3rd March 1995

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 ("the principal Regulations") which came into force on 14 February 1994 and introduced a new, simplified registration procedure for the marketing of certain homoeopathic medicinal products for human use.

These Regulations reduce by 5% the fees payable under Part III of the principal Regulations in respect of applications for the grant of (regulation 4), and for variations of (regulation 3), certificates of registration granted under the principal Regulations.

In addition these Regulations remove an anomaly in the principal Regulations. Regulation 5(4) of the principal Regulations prescribes the cases in which the licensing authority must, before refusing to grant a certificate of registration, consult the Advisory Board on the Registration of Homoeopathic Products. Regulation 2 of these Regulations substitutes a new regulation 5(4) of the principal Regulations in order to exclude from that duty to consult the case where a refusal of a certificate is required by virtue of regulation 5(2)(c) of the principal Regulations on the ground that the product has an insufficient degree of dilution within the meaning of regulation 5(3).