This Statutory Instrument has been made in consequence of errors in S.I.1994/105 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

1994 No. 899

MEDICINES

The Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 1994

Made - - - -	*24th March 1994*
Laid before Parliament	*30th March 1994*
Coming into force - -	*20th April 1994*

The Secretary of State, in exercise of the powers conferred upon 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 1994 and shall come into force on 20th April 1994.

(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.—(1) Regulation 5 of the principal Regulations (determination of application for certificate) shall be amended in accordance with the following paragraphs.

(2) In paragraph (2), for "paragraph (3)" there shall be substituted "paragraph (4)".

(3) For paragraph (3), there shall be substituted the following paragraph—

"(3) A product shall not be considered to have a sufficient degree of dilution to guarantee its safety if—

(a) in the case of a product containing an active principle whose presence in an allopathic medicinal product would require it to be sold by retail or supplied in

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

circumstances corresponding to retail sale in accordance with a prescription given by a doctor, it contains either more than one part per 10,000 of the mother tincture or more than one hundredth of the smallest dose of that active principle used in allopathy, or

(b) in any other case, it contains more than one part per 10,000 of the mother tincture.".

Amendment of regulation 9 of the principal Regulations

3. For paragraph (2) of regulation 9 of the principal Regulations (suspension and revocation) there shall be substituted the following paragraph—

"(2) Before suspending or revoking a certificate of registration on a ground set out in paragraph (1)(a) or (b) above, the licensing authority shall consult the Board, except in a case to which paragraph 11 of Schedule 2 to the Act, as applied by these Regulations, applies (procedure in the case of urgency).".

Amendment of Schedule 4 to the principal Regulations

4.—(1) Schedule 4 to the principal Regulations (application of provisions of the Act) shall be amended in accordance with the following paragraphs.

(2) In the modification to section 92 of the Medicines Act 1968(**4**), for "has though" there shall be substituted "as though".

(3) In the first modification to section 107 of that Act, for "1993" there shall be substituted "1994".

(4) For the first modification to Schedule 2 to that Act, there shall be substituted the following—

"as though for "the licence"and "licence" (wherever those words appear) there were substituted "the certificate" and "certificate", respectively;".

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State,
Department of Health

24th March 1994

(**4**) 1968 c. 67.

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.

Regulation 2(3) substitutes regulation 5(3) of the principal Regulations, in order to make it clearer. Regulation 5(3) sets out the criteria for determining whether a product is to be considered to have a sufficient degree of dilution to guarantee its safety: regulation 5(2) of the principal Regulations requires the licensing authority to refuse to grant a certificate of registration in respect of a homoeopathic medicinal product if the product does not have that sufficient degree of dilution.

Regulation 3 substitutes regulation 9(2) of the principal Regulations to require the licensing authority to consult the Advisory Board on the Registration of Homoeopathic Products before revocation, as well as before nsion, of a certificate of registration (except in cases of emergency). Regulations 2(2) and 4 make drafting amendments.