STATUTORY INSTRUMENTS

1994 No. 105

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

PART I

GENERAL

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 and shall come into force on 14th February 1994.

(2) In these Regulations:

"the Act" means the Medicines Act 1968(**1**);

"the Board" means the Advisory Board on the Registration of Homoeopathic Products(**2**);

"certificate of registration" means a certificate for the purposes of these Regulations;

"homoeopathic medicinal product" means a medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

and any expression used in these Regulations which is defined in the Act shall bear the meaning which it has in the Act.

(3) In these Regulations—

(a) any reference to doing anything in accordance with a certificate of registration shall be construed in the same way as a reference to doing anything in accordance with a licence under Part II of the Act is to be construed by section 132(3) of the Act (general interpretation provisions);

(b) any reference to the holder of a certificate of registration shall be construed as a reference to the holder of such a certificate which is for the time being in force; and

(c) any reference to placing a product on the market shall be construed in accordance with Council Directive 92/73/EEC(**3**).

(**1**) 1968 c. 67.
(**2**) The Board is established by S.I. 1994/102.
(**3**) OJ No. L297, 13.10.92, p.8.

Application

2. These Regulations shall apply to homoeopathic medicinal products for human use other than those prepared in accordance with a magistral or officinal formula as defined in Article 1(4) and (5) of the 1965 Directive(**4**) or which satisfy the criteria laid down in Article 2(4) of that Directive.

Placing on the market

3. A certificate of registration shall authorise the placing on the market of a homoeopathic medicinal product to which these Regulations apply.

(**4**) The definition of "the 1965 Directive", inserted into section 132(1) of the Act by regulation 3 of S.I. 1992/3271, is amended by S.I. 1994/101.