STATUTORY INSTRUMENTS

1994 No. 104

The Medicines (Labelling and Leaflets) Amendment Regulations 1994

Amendment of regulation 2(1) of the Leaflets Regulations

5.—(1) Regulation 2(1) of the Leaflets Regulations (interpretation) shall be amended in accordance with the following paragraphs of this regulation.

(2) After the definition of "the Act"there shall be inserted the following definition—

""certificate of registration" means a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;"(**1**).

(3) After the definition of "generator" there shall be inserted the following definitions—

""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;

"homoeopathic product to which Council Directive 92/73/EEC(**2**) applies" means a homoeopathic medicinal product for human use other than one—

(i) prepared in accordance with a magistral or officinal formula as defined in Article 1(4) and (5) of the 1965 Directive, or

(ii) which satisfies the criteria laid down in Article 2(4) of the 1965 Directive;".

(4) In the definition of "product to which Chapters II to V of the 1965 Directive apply"(**3**) for "and Article 1 of Council Directive 89/381/EEC(e)" there shall be substituted ", Article 1 of Council Directive 89/381/EEC(e) and Article 9(1) of Council Directive 92/73/EEC".

(5) In the definition of "proprietary medicinal product", for "but does not include a homoeopathic medicinal product or" there shall be substituted "including a homoeopathic product to which Council Directive 92/73/EEC applies, but does not include a".

(**1**) S.I.1994/105.
(**2**) OJNo. L297, 13.10.92, p. 8.
(**3**) Definition inserted by regulation 2(2) of S.I. 1992/3274.