
STATUTORY INSTRUMENTS

1994 No. 104

**The Medicines (Labelling and Leaflets)
Amendment Regulations 1994**

Insertion of regulation 4F into the Labelling Regulations

3. After regulation 4E of the Labelling Regulations, there shall be inserted the following regulation—

“Standard labelling requirements for containers and packages of certain homoeopathic products

4F.—(1) Containers and packages of homoeopathic products to which Council Directive [92/73/EEC](#) applies shall be labelled in clear and legible form to show a reference to their homoeopathic nature, in particular by clear mention of the words “homoeopathic medicinal product”, in addition to any particulars required by any other provision of these regulations.

(2) Where products referred to in paragraph (1) above are placed on the market in accordance with a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994⁽¹⁾, containers and packages of such products shall be labelled to show the particulars set out in Schedule 9 to these regulations and no other particulars.

(3) Regulations 5, 11, 14A to E, 15 and 16 of these regulations shall not apply in relation to products referred to in paragraph (2) above.”