STATUTORY INSTRUMENTS

2002 No. 236

The Medicines (Codification Amendments Etc.) Regulations 2002 (revoked)

Amendment of the Labelling Regulations 1976

5. The Medicines (Labelling) Regulations 1976 [M1] are amended as follows—

(a) in regulation 3(1) (interpretation)—

(i) after the definition of "data sheet" there is inserted the following definition—

""the 2001 Directive" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use;",

(ii) for the definition of "homoeopathic product to which Council Directive 92/73/EEC applies" there is substituted—

""homoeopathic product to which the 2001 Directive applies" means a medicinal product for human use (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, other than one—

(i) prepared in accordance with a magistral or officinal formula as described in Article 3(1) and (2) of the 2001 Directive, or

(ii) which satisfies the criteria laid down in Article 5 of the 2001 Directive;",

(iii) the definition of "product to which Chapters II to V of the 1965 Directive applies" is deleted, and

(iv) in the definition of "relevant medicinal product" for "Chapters II to V of the 1965 Directive" there is substituted " the 2001 Directive ";

(b) in regulation 4A (standard labelling requirement), in paragraph (5)—

(i) for the words from "Article 4a of Directive 65/65/EEC" to "Directive 89/341/EEC" inclusive there is substituted " Article 11.1 to 11.7 of the 2001 Directive ", and

(ii) in sub-paragraph (b), for "Article 4a of Directive 65/65/EEC" there is substituted " Article 11.1 to 11.7 of the 2001 Directive ";

(c) in regulation 4B (standard labelling requirements for radiopharmaceuticals) for "Chapters II to V of the 1965 Directive" there is substituted " the 2001 Directive "; and

(d) in regulation 4F (standard labelling requirements for certain homoeopathic products), in paragraph (1) for "Council Directive 92/73/EEC" there is substituted " the 2001 Directive ".

Marginal Citations

M1 S.I. 1976/1726; relevant amendments were made by S.I. 1992/3273, 1994/104 and 3144 and 1996/2194.