STATUTORY INSTRUMENTS

2002 No. 236

The Medicines (Codification Amendments Etc.) Regulations 2002

Amendment of the Standard Provisions Regulations 1971

3. The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**1**) are amended as follows—

(a) in regulation 2(1) (interpretation)—

(i) after the definition of ""clinical trial certificate of right" and "animal test certificate of right"" 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 medicines for human use;",

(ii) in the definition of "exempt imported products" for "article 1(2) of Council Directive 65/65/EEC" there is substituted "Article 1.2 of the 2001 Directive",

(iii) for the definition of "product to which Chapters II to V of the 1965 Directive apply" there is substituted the following definition—

""product to which the provisions of the 2001 Directive apply" means a medicinal product to which, in accordance with Article 2 of the 2001 Directive, the provisions of that Directive apply and accordingly does not include the products mentioned in Article 3 of that Directive;", and

(iv) the definition of "Second Council Directive" is omitted;

(b) in Schedule 1 (standard provisions for product licences), in paragraph 16 for "Part 4G of the Annex to Council Directive 75/318/EEC" there is substituted "Part 4G of Annex I to the 2001 Directive";

(c) in Schedule 2 (standard provisions for manufacturer's licences), in paragraph 16(1) and (4) for "Articles 23 and 24 of the Second Council Directive", in each place where those words occur, there is substituted "Articles 49 and 50 of the 2001 Directive";

(d) in Schedule 3 (standard provisions for wholesale dealer's licences)—

(i) in paragraphs 4A, 4B(1), 7A(1), 7B and 7C(1) for "Chapters II to V of the 1965 Directive", in each place where those words occur, there is substituted "the provisions of the 2001 Directive",

(ii) in paragraphs 7(3)(a), 8(1) and (6) for "Articles 23 and 24 of the Second Council Directive", in each place where those words occur, there is substituted "Articles 49 and 50 of the 2001 Directive", and

(iii) in paragraph 8(1) for "Article 24" there is substituted "Article 50"; and

(**1**) S.I.1971/972; relevant amendments were made by S.I. 1977/1053, 1993/833, 1994/103 and 1992/3272.

(e) in Schedule 5, Part I (standard provisions for product licences for medicinal products to which regulation 5 of the Standard Provisions Regulations applies), in paragraph 3A for "Council Directive 65/65/EEC as amended" there is substituted "the 2001 Directive".