
STATUTORY INSTRUMENTS

2005 No. 2759

**The Medicines (Marketing Authorisations
Etc.) Amendment Regulations 2005**

Amendments of the Patents Act 1977

3. In section 60 of the Patents Act 1977⁽¹⁾ (meaning of infringement)—
- (a) in subsection (5), after paragraph (h), insert the following—
- “(i) it consists of—
- (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive [2001/82/EC](#) or paragraphs 1 to 4 of article 10 of Directive [2001/83/EC](#), or
- (ii) any other act which is required for the purpose of the application of those paragraphs.”, and
- (b) in subsection (7), at the end insert the following—
- ““Directive [2001/82/EC](#)” means Directive [2001/82/EC](#) of the European Parliament and of the Council on the Community code relating to veterinary medicinal products⁽²⁾ as amended by Directive 2004/28 of the European Parliament and of the Council⁽³⁾;
- “Directive [2001/83/EC](#)” means Directive [2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by Directive [2002/98/EC](#) of the European Parliament and of the Council, by Commission Directive [2003/63/EC](#) and by Directives [2004/24/EC](#) and [2004/27/EC](#) of the European Parliament and of the Council”.

⁽¹⁾ 1977 c. 37.

⁽²⁾ OJNo. L311, 28.11.2001, p.1.

⁽³⁾ OJ No. L136, 30.4.2004, p.58.