STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

Applications relating to generic medicinal products

51.—(1) An applicant for a UK marketing authorisation for a relevant medicinal product that is a generic medicinal product may provide information in relation to the application in accordance with Article 10(1), (5) and (6) of the 2001 Directive.

(2) If the licensing authority grants a UK marketing authorisation for the generic medicinal product in accordance with paragraph (1), it is a term of the authorisation that the product must not be sold or supplied, or offered for sale or supply, in the United Kingdom before the time at which it may be placed on the market in accordance with—

(a) Article 10(1) of the 2001 Directive; or

(b) in a case where the application for the marketing authorisation for the reference medicinal product referred to in the application was submitted on or before 30th October 2005, Article 10(1) of the 2001 Directive as it stood before it was amended by Article 1(8) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending the 2001 Directive(**1**) ("Directive 2004/27/EC"), in accordance with Article 2 of Directive 2004/27/EC .

(**1**) OJ No L 136, 30.4.2004, p. 34.