STATUTORY INSTRUMENTS

2012 No. 504

The Medicines (Products for Human Use) (Fees) Regulations 2012

PART 8

Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorizations

Fees for regulatory assistance for certain marketing authorizations

26.—(1) Where—

(a) an application is made to the licensing authority for the renewal of a United Kingdom marketing authorization for a medicinal product which has been subject to the procedures specified in paragraph (2); and

(b) the United Kingdom is to provide regulatory assistance acting as reference Member State in relation to that application,

the fee payable by the applicant is the fee prescribed in Part 6 of Schedule 2 in connection with that regulatory assistance.

(2) The procedures referred to in paragraph (1) are—

(a) the procedures laid down in Articles 7 and 7a of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products(**1**) and in Articles 17 and 18 of the 2001 Directive;

(b) the procedures laid down in Article 9(4) of Directive 75/319/EEC and in Article 28 of the 2001 Directive;

(c) the procedures laid down in Articles 10 to 14 of Directive 75/319/EEC and in Articles 29 to 34 of the 2001 Directive;

(d) referral to the Committee for Proprietary Medicinal Products in accordance with Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology(**2**), if the opinion of the Committee in accordance with Article 4(1) of that Directive was given before 1st January 1995.

(3) For the purposes of this regulation and Part 6 of Schedule 2, the United Kingdom provides regulatory assistance acting as reference Member State if—

(a) the licensing authority prepares or updates an assessment report in respect of the medicinal product to which the renewal application relates in order to make it available to the competent authorities of another EEA State; and

(**1**) OJ No. L 22, 9.2.1965, p.369. This Directive has been codified and assembled with others into Directive 2001/83/EC.
(**2**) OJ No. L 15, 17.1.1987, p.38. This Directive has been repealed by Council Directive 93/41/EEC, OJ No. L 214, 24.8.1993, p.40.

(b) an application to renew the marketing authorization relating to that product has been made in that other EEA State.