STATUTORY INSTRUMENTS

2012 No. 504

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

PART 5

Capital Fees for Applications for Variations of Authorizations, Registrations, Licences and Authorisations and for Associated Inspections

Fees for variations of authorizations, registrations, licences and authorisations

18.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the fee for an application—

(a) under regulation 4 (applications for the grant, renewal or variation of a United Kingdom marketing authorization) of the Marketing Authorisation Regulations(**1**) for the variation of a United Kingdom marketing authorization;

(b) under regulation 6 (consideration and grant or refusal, of an application for, or for renewal or variation of, a traditional herbal registration) of the Herbal Regulations for the variation of a traditional herbal registration;

(c) under section 30 (variation of licence on application of holder) of the Act(**2**) for the variation of a product licence, a manufacturer's licence or a wholesale dealer's licence; or

(d) under regulation 44 (variation of manufacturing authorisation) of the Clinical Trials Regulations(**3**) for the variation of a manufacturing authorisation,

is the fee mentioned in paragraph (2).

(2) The fee referred to in paragraph (1) is—

(a) the fee prescribed in Part 4 of Schedule 2 in connection with the application; and

(b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 27 to 29 and 31.

(3) Unless regulation 28 applies, the fee in paragraph (1) is payable by the applicant.

(**1**) Regulation 4 has been amended by S.I. 2001/795, 2002/236, 2005/2759, 2006/1952.
(**2**) Section 30 was substituted by S.I. 2005/2789.
(**3**) Regulation 44 has been amended by S.I. 2006/1928, 2010/551.