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STATUTORY INSTRUMENTS

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**2010 No. 551**

The Medicines (Products for Human  
Use) (Fees) Regulations 2010

PART 4

Capital Fees for Assistance in Obtaining  
Marketing Authorizations in Other EEA States

**Meaning of “set of applications”**

**15.** For the purposes of this Part, a “set of applications” means—

- (a) a number of applications to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorization in other EEA States, but only if all the applications relate to applications for marketing authorizations in other EEA States that have the same 90 day assessment period for the purposes of Article 28.4 of the 2001 Directive; or
- (b) a number of applications to competent authorities of other EEA States for marketing authorizations relating to a single United Kingdom marketing authorization, but only if all the applications have the same 90 day assessment period for the purposes of Article 28.4 of the 2001 Directive.

**Fees for applications for regulatory assistance under the mutual recognition procedure**

**16.** The fee payable by an applicant to the licensing authority for regulatory assistance in connection with obtaining recognition according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive of a single United Kingdom marketing authorization in another EEA State or in other EEA States, is the fee prescribed in Part 3 of Schedule 1 in connection with the application or set of applications.

**Time for payment of fees under regulation 16**

**17.** Unless regulation 41 (applications made by small companies) applies, all sums payable by way of fees under regulation 16 must be paid at the time when, in connection with the application or set of applications for regulatory assistance, a request is made pursuant to the second sub-paragraph of Article 28.1 of the 2001 Directive for an assessment report to be prepared or updated.