STATUTORY INSTRUMENTS

2012 No. 504

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

PART 3

Capital Fees for Applications for Authorizations, Registrations, Licences, Certificates or Authorisations and for Associated Inspections

Fees for applications for authorizations, licences or certificates etc.

12.—(1) Unless Part 16 of these Regulations (revocations and savings) applies, the application fee for a marketing authorization (other than a European Union marketing authorization), a traditional herbal registration, a manufacturer's licence, a manufacturing authorisation, a wholesale dealer's licence or a clinical trial authorisation is—

(a) the fee prescribed for that application in Part 2 of Schedule 2; and

(b) in respect of an inspection of a site made in connection with that application, the fee payable in accordance with regulations 27 to 32.

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