STATUTORY INSTRUMENTS

2010 No. 551

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

PART 9

Capital Fees for Inspections

Fees for inspections

27.—(1) Unless regulation 52 (revocations and savings) applies, a fee is payable in accordance with—

(a) paragraphs 1 to 7 of Schedule 2 for any inspection of a site made in connection with an application for, or during the currency of, a marketing authorization, a traditional herbal registration, a clinical trial authorisation, a manufacturing authorisation, a manufacturer's licence or a wholesale dealer's licence, except for an inspection for which a fee is payable under regulations 24 or 30; and

(b) paragraphs 1 and 8 of Schedule 2 for any inspection comprising an office-based evaluation and risk assessment of documentation but not involving inspection of a site, in connection with the monitoring of—

(i) good manufacturing practice;

(ii) good clinical practice;

(iii) good pharmacovigilance practice; or

(iv) good distribution practice.

(2) Unless regulation 28 or 29 applies, the fee in paragraph (1) is payable by the holder of, or as the case may be, applicant for, the authorization, registration, authorisation or licence in relation to which the inspection is made.