STATUTORY INSTRUMENTS

2010 No. 551

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

PART 9

Capital Fees for Inspections

Inspections in connection with multiple applications

29.—(1) Unless paragraph (4) applies, where an inspection is made outside the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or for the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

(a) in more than one marketing authorization, clinical trial authorisation, traditional herbal registration; or

(b) by more than one applicant for such an authorisation or licence,

the fee for the inspection referred to in regulation 27(1) is payable in equal proportions by the holders of, or as the case may be, applicants for, the authorization, registration, authorisation, or licence.

(2) In paragraph (1), the reference to an applicant for a clinical trial authorisation is a reference to a person who sends a valid notice of amendment as mentioned in regulation 19(1).

(3) Where an inspection is made in the United Kingdom at a site which is named as a possible site for the manufacture or assembly of a medicinal product, or the preparation of a substance which is to be used in the manufacture of an immunological product or a blood product—

(a) in more than one manufacturer's licence or manufacturing authorisation; or

(b) by more than one applicant for such a licence or authorisation,

the fee for the inspection referred to in regulation 27(1) is payable in equal proportions by each applicant.

(4) This regulation does not apply if the inspection is made of a contract laboratory or a site used by an API manufacturer.