STATUTORY INSTRUMENTS

2016 No. 190

The Medicines (Products for Human Use) (Fees) Regulations 2016

PART 9

Capital Fees for Inspections

Fees for inspections

30.—(1) Unless regulation 31 or Part 16 of these Regulations applies, a fee is payable in accordance with—

(a) paragraphs 1 to 9 of Schedule 3 for inspection of any site made in connection with an application for, or during the currency of, a marketing authorisation, a traditional herbal registration, a clinical trial authorisation, a manufacturing authorisation, a manufacturer's licence a wholesale dealer's licence, a broker's registration or an active substance registration except for an inspection for which a fee is payable under regulation 27 or 34;

(b) paragraph 10 of Schedule 3 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 32 or 33 applies, the fee in paragraph (1) is payable by the holder of, or as the case may be, applicant for, the authorisation, registration or licence in relation to which the inspection is made.

Fees for inspections of pharmacovigilance service providers

31.—(1) Where an inspection is made of a pharmacovigilance service provider and that inspection is not related to anything done under regulation 30(1)(a), a fee is payable in accordance with paragraphs 1 and 2 of Schedule 3.

(2) The fee in paragraph (1) is payable by the pharmacovigilance service provider who is the subject of an inspection.

(3) In this regulation a "pharmacovigilance service provider" means a provider of pharmacovigilance services to a marketing authorisation holder.

Payer of inspection fee (contract laboratories and API manufacturing sites)

32. Where an inspection is made of a contract laboratory or a site used by an API manufacturer the fee is payable by the operator of that laboratory, or as the case may be, that API manufacturer.

Inspections in connection with multiple applications

33.—(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 authorisation, clinical trial authorisation, traditional herbal registration; or

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

the fee for the inspection referred to in regulation 30(1) is payable in equal proportions by the holders of, or as the case may be, applicants for, the authorisation, registration 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 20(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 30(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.

Fees for inspections relating to good clinical practice in clinical trials

34. A fee in accordance with paragraph 2 of Schedule 3 is payable by a person in respect of an inspection of one or more sites for the purpose of ascertaining whether that person—

(a) is—

(i) conducting, or has conducted, a clinical trial, or

(ii) performing, or has performed, the functions of a sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),

in accordance with good clinical practice, under regulation 28(1) (good clinical practice and protection of clinical trial subjects) of the Clinical Trials Regulations; or

(b) has put and kept in place arrangements for the purpose of ensuring that with regard to a clinical trial the requirements of good clinical practice are satisfied or adhered to, under regulation 28(2) of those Regulations.

Amount, and time for payment, of inspection fees in respect of an application for a wholesale dealer's licence

35.—(1) All sums payable by way of fees in respect of any inspection of a site in connection with an application for a wholesale dealer's licence under regulation 30(1) must be paid—

(a) in advance of an application; or

(b) at the time that application is made.

(2) Except where paragraph (3) applies, the inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 5(a) of Schedule 3.

(3) The inspection fee payable as a consequence of paragraph (1) shall be the amount specified in paragraph 7(3) of Schedule 3 where—

(a) the site to be inspected falls within the description specified in paragraph 7(1)(a) or (b) of Schedule 3; or

(b) the total turnover in respect of sales by way of wholesale dealing in authorised medicinal products of the wholesale dealer does not exceed £35,000 (within the meaning given in paragraph 7(2) of that Schedule)**.**

Adjustment and refund of inspection fees in respect of a wholesale dealer's licence

36.—(1) If the inspection in respect of an application for a wholesale dealer's licence takes longer than the standard period, a further fee of the amount specified in paragraph 5(b) of Schedule 3 is payable by the applicant for each subsequent period of 3 hours and 30 minutes or less.

(2) The fee payable under paragraph (1) must be paid within a period of 14 days commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

(3) The licensing authority shall refund the whole of the inspection fee paid where, after an inspection fee is paid as a consequence of regulation 35, the application for a wholesale dealer's licence is withdrawn—

(a) before a date on which the inspection is due to take place is arranged with or notified to the applicant; or

(b) in the case where a date on which the inspection is due to take place is fixed, 15 or more days before the date on which that inspection is due to take place.

(4) In this regulation "standard period" means—

(a) in the case where regulation 35(2) applies, a period of more than 7 hours; or

(b) in the case where regulation 35(3) applies, a period of more than 3 hours and 30 minutes.

Amount, and time for payment, of inspection fees in respect of an application for a broker's registration or an active substance registration

37.—(1) All sums payable by way of fees in respect of any assessment or inspection of a site in connection with an application for a broker's registration or an active substance registration under regulation 30(1) must be paid in advance of an application or at the time the application is made.

(2) The inspection fee payable as a consequence of paragraph (1) shall be—

(a) in relation to broker's registrations, the amount specified in paragraph 8(1) of Schedule 3;

(b) in relation to active substance registrations, the amount specified in paragraph 9(1) of Schedule 3.