STATUTORY INSTRUMENTS

2010 No. 551

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

PART 10

Periodic Fees for Authorizations, Registrations, Licences and Authorisations

Periodic fees

33.—(1) Unless paragraphs (4), (5) or (6) or regulation 52 (revocations and savings) applies, the periodic fee must be paid for each fee period during which the marketing authorization, registration, authorisation or licence is in force, even if it is in force for only part of that fee period.

(2) For the purposes of paragraph (1), marketing authorizations of a type referred to in Part 3 of Schedule 3 shall be treated as if they were one marketing authorization and only one periodic fee in respect of each relevant fee period is payable in connection with the holding of such authorizations.

(3) The periodic fee is the appropriate fee prescribed in Part 3 of Schedule 3 and, for the purposes of that Part, Parts 1 and 2 of that Schedule have effect.

(4) No periodic fee is payable in respect of the fee period during which a marketing authorization or a traditional herbal registration is first granted unless the authorization or registration is granted pursuant to—

(a) a change of ownership application; or

(b) an application for a marketing authorization or traditional herbal registration which—

(i) is for a product for which an authorization or registration has expired;

(ii) will contain identical provisions to those contained in the expired authorization or registration;

(iii) is made by the person who held the expired authorization or registration; and

(iv) is made no later than three months after the expiry of the authorization or registration referred to in paragraph (i),

and, in each case, a periodic fee has not been paid in respect of that fee period in connection with the expired marketing authorization or a traditional herbal registration.

(5) An authorization, registration, authorisation or licence which is in force is treated for the purposes of this regulation as not being in force during any part of a fee period if—

(a) at least three months before the commencement of that fee period, the holder of that authorization, registration, authorisation or licence has given written notice to the licensing authority indicating that he wishes it to cease to have effect before the commencement of that period; and

(b) no products are sold, supplied or manufactured pursuant to that authorization, registration authorisation or licence within that fee period.

(6) No periodic fee is payable in respect of the fee period during which a manufacturing authorisation, a manufacturer's licence or wholesale dealer's licence is first granted unless—

(a) that authorisation or licence is granted pursuant to a change of ownership application; and

(b) a periodic fee has not been paid in respect of that fee period in connection with the manufacturing authorisation or manufacturer's licence or wholesale dealer's licence which is mentioned in that application in the statement of intention to cease activities.

Periodic fees for clinical trial authorisations

34.—(1) Unless paragraph (3) applies, the holder of a clinical trial authorisation must pay the periodic fee for each fee period during which the authorisation is in force, even if the authorisation is in force for only part of that fee period.

(2) The periodic fee is the fee prescribed in paragraph 16 of Part 3 of Schedule 3.

(3) No periodic fee is payable in respect of the fee period during which the clinical trial to which the authorisation relates was authorised by the licensing authority in accordance with regulation 18 (authorisation procedure for clinical trials involving general medicinal products), 19 (authorisation procedure for clinical trials involving medicinal products for gene therapy etc.) or 20 (authorisation procedure for clinical trials involving medicinal products with special characteristics) of the Clinical Trials Regulations(**1**).

(**1**) Regulation 19 has been amended by S.I. 2005/2754.