EXTRACT TAKEN FROM THE MEDICINES (PRODUCTS FOR HUMAN USE) (FEES) REGULATIONS 2013 No 532

Regulation 49 (1)

Time for Payment of Capital Fees for small companies

Interpretation

1. In this Schedule a reference to an application is to an application made by or on behalf of a small company.

Major application

2. In connection with a major application for a marketing authorisation for which the fee payable is that specified in entry 1(f) of the table in paragraph 24 of Part 2 of Schedule 2, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 25% at the time of the application and as to 75% within 30 days following written notice from the licensing authority that the application has been determined.

Complex application

3. In connection with a complex application for a marketing authorisation, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable—

(a) as to 50% at the time of the application; and

(b) as to 50% within 30 days following written notice from the licensing authority that the application has been determined.

Multiple application

4. In connection with an application to which paragraph 28 of Part 2 of Schedule 2 applies, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable—

(a) as to 50% of the total payable in accordance with that paragraph at the time of the application; and

(b) as to 50% of that total within 30 days following written notice from the licensing authority that the application has been determined.

Outgoing mutual recognition application

5. As regards the fee payable under regulation 16 in connection with an application—

(a) to which paragraph 36(2) of Part 3 of Schedule 2 applies—

(i) 25% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under the second sub-paragraph of Article 28(1) of the 2001 Directive for an assessment report to be prepared or updated; and

(ii) 75% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end;

(b) to which paragraph 36(3), (4) or (5), of Part 3 of Schedule 2 applies—

(i) 50% of that fee shall be payable at the time when, in connection with the application or set of applications for regulatory assistance, a request is made under the second sub-paragraph of Article 28(1) of the 2001 Directive for an assessment report to be prepared or updated, and

(ii) 50% of that fee shall become payable within 30 days following written notice from the licensing authority that the regulatory assistance is at an end,

if the applicant so requests in writing.

Application for traditional herbal registration

6. In connection with an application for a traditional herbal registration, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Traditional herbal registration: complex variation

7. In connection with a complex variation application or a new excipient variation application to vary a traditional herbal registration, the fee payable under regulation 18(1) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Application for manufacturer's licence, manufacturing authorisation or wholesale dealer's licence

8. In connection with an application for a manufacturer's licence, manufacturing authorisation, or a wholesale dealer's licence, the fee payable under regulation 12(1)(a) shall, if the applicant so requests in writing, be payable as to 50% at the time of the application and as to 50% within 12 months after that time.

Inspection fees in connection with applications

9. In connection with an application for a marketing authorisation, traditional herbal registration, manufacturer's licence or manufacturing authorisation, the fee payable in respect of an inspection at any site other than one named as a possible site for manufacture of a medicinal product by three or more applicants shall, if the applicant so requests in writing, be payable as to 50% within the period of 14 days referred to in regulation 48(1)(b) and as to 50% within 12 months after that date.