

SCHEDULE 4

Regulation 41(1)

TIME FOR PAYMENT OF CAPITAL FEES

Interpretation

1.—(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 authorization for which the fee payable is that specified in entry 1(f) of the table in paragraph 24 of Part 2 of Schedule 1, 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 authorization, 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 1 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 aggregate payable in accordance with that paragraph at the time of the application; and
- (b) as to 50% of that aggregate 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 34(2) of Part 3 of Schedule 1 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 pursuant to 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 34(3), (4) or (5), of Part 3 of Schedule 1 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 pursuant to the second sub-paragraph of Article 28.1 of the 2001 Directive for an assessment report to be prepared or updated, and

Status: This is the original version (as it was originally made).

(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 authorization, 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 40(1)(b) and as to 50% within 12 months after that date.