
STATUTORY INSTRUMENTS

1995 No. 1116

The Medicines (Products for Human
Use — Fees) Regulations 1995

PART VII

ADMINISTRATION

Payment of fees to Ministers

15. Any sums which under the provisions of these Regulations become payable by way of, or on account of, fees shall be paid to one of the Ministers specified in section 1(1)(a) (Ministers responsible for the administration of the Act) of the Act.

Time for payment of capital fees in connection with applications or inspections

16.—(1) Subject to paragraph (2) and to regulations 17 and 19, all sums payable by way of capital fees under these Regulations in connection with any application shall be payable at the time of the application.

(2) All sums payable by way of fees in respect of inspections made either in connection with an application for, or during the currency of, an authorization, licence or certificate shall become payable within 14 days following written notice from the licensing authority requiring payment of those fees.

Time for payment of capital fees applications made by small companies

17.—(1) Schedule 4 shall have effect with respect to the capital fee payable in connection with an application made by or on behalf of a small company.

(2) For the purpose of these Regulations, a company is a small company if, for the financial year before that in which the application is made, the amount of its turnover for the financial year is not more than the amount for the time being specified under the heading “*Small company*” in section 247(3) (qualification of company as small or medium-sized) of the Companies Act 1985(1); and

- (a) its balance sheet total (as defined in section 247(5) of that Act) is not more than the amount for the time being specified under the heading “*Small company*” in section 247(3) of that Act; or
- (b) the average number of persons employed by the company in the financial year before that in which the application is made (determined on a weekly basis) does not exceed the number for the time being specified under the heading “*Small company*” in section 247(3) of that Act.

(1) 1985 c. 6 as amended by section 13(1) of the Companies Act 1989 (c. 40) and by regulation 5(3) of the Companies Act 1985 (Accounts of Small and Medium-Sized Enterprises and Publication of Accounts in ECUs) Regulations 1992 (S.I.1992/2452). On 1st March 1995 the figures specified in section 247(3) under the heading “*Small company*” applying to the turnover, balance sheet total and number of employees respectively were, £2.8 million, £1.4 million and 50.

Time for payment of periodic fees

18. All periodic fees shall be payable on the first day of the fee period to which they relate.

Adjustment, waiver, reduction or refund of fees

19.—(1) If after a capital or periodic fee was paid it becomes apparent that—

- (a) a lesser fee was properly payable, the excess shall be refunded to the applicant or, as the case may be, the holder of the authorization, licence or certificate concerned: or
- (b) a higher fee was properly payable, the balance due shall be payable within 14 days following written notice from the licensing authority to the applicant or, as the case may be, the holder of the authorization, licence or certificate concerned requiring payment of that balance.

(2) The licensing authority shall, to the extent provided in Schedule 5 in relation to capital fees or in Schedule 6 in relation to periodic fees,—

- (a) adjust, waive payment of or reduce any fee or part of a fee otherwise payable under these Regulations; or
- (b) refund the whole or part of any fee already paid.

Suspension of licences and certificates

20. Where any sum due by way of, or on account of, any fee or any part thereof payable under these Regulations remains unpaid by the holder of a product licence or a product licence of right, a manufacturer's licence, a wholesale dealer's licence or a clinical trial certificate, the licensing authority may serve a written notice on him requiring payment of the sum unpaid and, if after a period of one month from the date of service of such notice, or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence or certificate until such sum has been paid.

Civil proceedings to recover unpaid fees

21. All unpaid sums due by way of, or on account of, any fees payable under these Regulations shall be recoverable as debts due to the Crown.