
STATUTORY INSTRUMENTS

1991 No. 1474

**The Medicines (Products for Human
Use — Fees) Regulations 1991**

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) 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, a 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 in section 248(1)(a) of the Companies Act 1985(1); and

- (a) its balance sheet total (as defined in section 248(3) of that Act) is not more than the amount for the time being specified in section 248(1)(b) 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 in section 248(1)(c) of that Act.

Time for payment of periodic fees

18.—(1) Subject to paragraph (2), all periodic fees shall be payable on the first day of the licence fee period to which they relate.

(1) 1985 c. 6, as amended by section 13(3) of the Companies Act 1989 (c. 40). The figures currently specified in section 248(1)(a), (b) and (c) are, respectively, £2 million, £975,000 and 50.

(2) Periodic fees payable in respect of the licence fee period beginning with the date of coming into force of these Regulations, shall be payable within 28 days of receipt of a written notice given by the licensing authority requiring payment of such fees.

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 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 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 or 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 licence or certificate, the licensing authority may serve a 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, that sum remains unpaid, the licensing authority may forthwith suspend the licence or certificate until that 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.