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STATUTORY INSTRUMENTS

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**2012 No. 504**

The Medicines (Products for Human  
Use) (Fees) Regulations 2012

PART 14

Administration

**Payment of fees to Ministers**

44. Any sum payable under these Regulations must be paid to one of the Ministers.

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

45.—(1) All capitals fees under these Regulations shall be payable in accordance with—

- (a) the specified provisions in paragraph (2) where appropriate, and
- (b) paragraph (3).

(2) The specified provisions are—

- (a) regulation 10 (pre-application meetings);
- (b) regulation 16 (regulatory assistance);
- (c) regulation 22 (change to labels and leaflets);
- (d) regulation 31 (inspections in respect of wholesale dealer's licence);
- (e) regulation 37 (person appointed hearings); and
- (f) regulation 46 (small companies).

(3) All fees payable under this regulation—

- (a) in respect of inspections made either in connection with an application for, or during the currency of, an authorization, licence or certificate must be paid within a period of 14 days commencing on the date of the written notice issued by the licensing authority requiring payment of those fees; and
- (b) in connection with any application, must have been paid at the time of the application or before.

**Time for payment of capital fees – applications made by small companies**

46.—(1) Schedule 6 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 total value of products it has sold or supplied for the financial year is not more than the amount for the time being specified under the heading “Small

company” in item 1 in section 382(3) (qualification of company as small) of the Companies Act 2006<sup>(1)</sup> and the conditions in paragraph (3) are met.

- (3) The conditions for the purposes of paragraph (2) are—
- (a) the company’s balance sheet total as defined in section 382(5) of the Companies Act 2006 is not more than the amount for the time being specified under the heading “Small company” in section 382(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 382(3) of that Act.

### **Payment of fees in respect of a traditional herbal registration**

47.—(1) Where an application is made for the grant of a traditional herbal registration—

- (a) in accordance with regulation 5 (applications for the grant or renewal of a traditional herbal registration) of the Herbal Regulations;
- (b) on the grounds specified in paragraph (2); and
- (c) in respect of a medicinal product which falls within the description in paragraph (3),

the fee payable under regulation 12 shall be refunded or, if it has not been paid, shall be waived.

(2) For the purposes of paragraph (1), the specified grounds are—

- (a) that the marketing authorization in respect of the medicinal product in question; or
- (b) in the case of a corresponding product the marketing authorization relating to product Y (as defined in paragraph (4)),

is to be revoked.

(3) A medicinal product falls within this paragraph if—

- (a) a marketing authorization held by the applicant was granted under the Marketing Authorisation Regulations in respect of that medicinal product; or
- (b) that medicinal product is a corresponding product.

(4) For the purposes of paragraph (3), a corresponding product is a product which is characterised by having—

- (a) the same active ingredients, irrespective of the excipients used or reduction in the number or quantity of active ingredients;
- (b) the same or similar intended purpose, equivalent strength and posology; and
- (c) the same or similar route of administration,

as a medicinal product (“product Y”) in respect of which a marketing authorization held by the applicant was granted under the Marketing Authorisation Regulations.

(5) Where the licensing authority determines that the marketing authorizations in respect of the medicinal product in question or the marketing authorization in respect of product Y should not be revoked, the fee payable under regulation 12 which has been refunded or waived shall become payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority requiring payment of those fees.

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(1) 2006 c.46. A relevant amendment was made by S.I. 2008/393.

### **Time for payment of periodic fees**

48. All periodic fees must be paid by the first day of the fee period to which they relate.

### **Penalty fees for late payment of periodic fees**

49.—(1) Subject to paragraph (2), if a person has failed to pay a periodic fee by the time it has become payable under regulation 48, a penalty fee is payable by that person.

(2) A penalty fee is payable only if, after a period of 60 days commencing on the date of the written notice (“the notice”) issued by the licensing authority requiring payment of that fee, the fee remains unpaid.

(3) Unless regulation 50 applies, where a periodic fee remains unpaid after 60 days commencing on the date of the notice, the penalty fee is—

- (a) £100 where the total unpaid fee exceeds £200; or
- (b) £50 where the total unpaid fee does not exceed £200.

(4) In paragraph (3), the “total periodic fee” means the total of all the periodic fees payable by a person in connection with all the authorizations, registrations, authorisations or licences held by that person.

### **Daily penalty fees for late payment of periodic fees**

50. If the periodic fee and penalty fee under regulation 49 (“the outstanding amount”) have not been paid within a period of 90 days commencing on the date of the written notice issued by the licensing authority, the amount of penalty fee payable shall be the amount specified in regulation 49(3) plus £5 for each day of the period which—

- (a) begins with the day 90 days from the date of the written notice; and
- (b) ends with the day before that on which payment of the outstanding amount is actually made.

### **Refund or waiver of fees under regulation 49 or 50**

51. The licensing authority may refund or waive payment of the penalty fee, or reduce the amount payable, where it is satisfied that the holder of the authorization, registration, authorisation or licence was not responsible for the failure to pay the periodic fee within the period specified in regulation 49(2) or 50.

### **Adjustment, waiver, reduction or refund of fees**

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

- (a) a lesser fee should have been paid, the excess shall be refunded to the applicant or, as the case may be, the holder of the authorization, registration, authorisation or licence concerned; or
- (b) a higher fee should have been paid, the balance due shall be payable within a period of 14 days commencing on the date of the written notice issued by the licensing authority to the applicant or, as the case may be, the holder of the authorization, registration, authorisation or licence concerned requiring payment of that balance.

(2) The licensing authority shall, to the extent provided in Schedule 7 in relation to capital fees or in Schedule 8 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 authorisations**

**53.**—(1) Where any sum due by way of, or on account of, any fee or any part of a fee payable under these Regulations remains unpaid by the holder of a—

- (a) product licence or a product licence of right;
- (b) manufacturer's licence;
- (c) manufacturer's authorisation; or
- (d) wholesale dealer's licence,

the licensing authority may serve a written notice on the holder requiring payment of the sum unpaid.

(2) If after a period of one month commencing on the date of service of the notice referred to in paragraph (1), or such longer period as the licensing authority may allow, the said sum remains unpaid, the licensing authority may forthwith suspend the licence or, as the case may be, the authorisation until such sum has been paid.

#### **Civil proceedings to recover unpaid fees**

**54.** 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.