

---

STATUTORY INSTRUMENTS

---

**2012 No. 504**

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

**PART 12**

**Capital Fee for a Person Appointed Hearing**

**Fee for a person appointed hearing**

**37.**—(1) The fee payable by an applicant or holder of an authorization, licence, authorisation or certificate of registration or sponsor or investigator who gives notice, under any of the provisions specified in paragraph (2), of their wish to make further representations to the licensing authority or appear before or be heard by a person appointed by the licensing authority, is £10,000.

(2) The specified provisions are—

- (a) section 21(11) (licence under Part I of the Act where the appropriate committee are consulted), 22(3) (licence under Part I of the Act where the appropriate committee are not consulted or have been consulted but have not given a provisional opinion) or 27(3) (licence of right) of the Act, and paragraph 5 (product licence) or paragraph 6 (licence under Part 2 of the Act other than a product licence) of Schedule 2 to the Act<sup>(1)</sup>;
- (b) paragraph 3 of Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials)<sup>(2)</sup> and paragraph 4 of Schedule 8 (procedural provisions relating proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations) to the Clinical Trials Regulations<sup>(3)</sup>;
- (c) paragraph 12 (traditional herbal registration), paragraph 17 (variation of registration) or paragraph 20 (decision to refer application to the Committee) of Schedule 2 to the Herbal Regulations;
- (d) paragraph 11 (marketing authorizations) or paragraph 16 (Type II variation applications) of Schedule 2 to the Marketing Authorisation Regulations<sup>(4)</sup>; or
- (e) paragraph 12 of Schedule 5 (procedural provisions relating to the grant, renewal, variation, revocation and suspension of certificates of registration) to the Homoeopathic Regulations<sup>(5)</sup>.

(3) The licensing authority will refund to that person—

- (a) 60% of that fee if the person withdraws the notice two weeks before the commencement of the hearing before the person appointed;

---

(1) Sections 21 and 22 were substituted by regulation 8 of, and paragraphs 2 and 3 of Schedule 1 to, [S.I. 2005/1094](#).  
(2) Schedule 5 was substituted by regulation 4 of, and paragraph 5 of Schedule 3 to, [S.I. 2005/2754](#).  
(3) Paragraph 4 was substituted by regulation 4 of, and paragraph 6 of Schedule 3 to, [S.I. 2005/2754](#).  
(4) Schedule 2 was substituted by regulation 9 of, and paragraph 4 of Schedule 2 to, [S.I. 2005/1094](#).  
(5) Schedule 5 was inserted by regulation 20 of [S.I. 2005/2753](#).

- (b) 100% of that fee if, in respect of the hearing before a person appointed, the decision notified by the licensing authority is—
  - (i) not to revoke, vary, suspend or terminate, as the case may be, the authorization, licence, authorisation or certificate of registration; or
  - (ii) to grant or renew, as the case may be, the authorization, licence, authorisation or certificate of registration.

**Time for payment under regulation 37**

- 38.** The fee prescribed in regulation 37 is payable at the time the notice is given.