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STATUTORY INSTRUMENTS

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**2010 No. 551**

**The Medicines (Products for Human  
Use) (Fees) Regulations 2010**

**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 appropriate committee are consulted), 22(3) (licence under Part I of the Act where 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 (authorisation to conduct a clinical trial or amendment to clinical trial authorisation) and paragraph 4 of Schedule 8 (manufacturing authorisation) to the Clinical Trials Regulations<sup>(2)</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; or
- (d) paragraph 11 (marketing authorizations) or paragraph 16 (Type II variation applications) of Schedule 2 to the Marketing Authorisation Regulations<sup>(3)</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;
- (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.

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<sup>(1)</sup> Sections 21 and 22 were substituted by regulation 8 of, and paragraphs 2 and 3 of Schedule 1 to, [S.I. 2005/1094](#).

<sup>(2)</sup> Paragraph 4 was substituted by regulation 4 of, and paragraph 6 of Schedule 3 to, [S.I. 2005/2754](#).

<sup>(3)</sup> Schedule 2 was substituted by regulation 9 of, and paragraph 4 of Schedule 2 to, [S.I. 2005/1094](#).

**Time for payment under regulation 37**

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