STATUTORY INSTRUMENTS

2008 No. 552

The Medicines (Products for Human Use-Fees) Regulations 2008

PART 12

Capital Fees for Persons Appointed Hearing

Fees for persons appointed hearing

35.—(1) The fee payable by an applicant or holder of an authorization who gives notice under paragraph 11 (right to be heard by a person appointed or to make further representations) or 16 (right to be heard by a person appointed) of Schedule 2 to the 1994 Regulations(**1**) of his wish to appear before or be heard by a person appointed by the licensing authority is £10,000.

(2) But 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 the decision notified by the licensing authority in accordance with sub-paragraph (10) of paragraph 17 (hearing before person appointed) of Schedule 2 to the 1994 Regulations is—

(i) not to revoke, vary or suspend the authorization, or

(ii) to grant or renew the authorization in accordance with the application submitted under regulation 4(1) (applications for the grant, renewal or variation of a UK marketing authorization) of the 1994 Regulations.

Time for payment under regulation 35

36. The fee in regulation 35 is payable at the time the notice is given.

(**1**) Schedule 2 was substituted by S.I. 2005/1094.