STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Request for authorisation to conduct a clinical trial

17.—(1) A request for authorisation to conduct a clinical trial shall be made to the licensing authority by the sponsor of the trial.

(2) **[**[F1]Subject to paragraph (2A), a**]** request shall—

(a) be in writing and signed by or on behalf of the sponsor; and

(b) be accompanied by—

(i) the particulars and documents specified in Part 2 of Schedule 3, and

(ii) any fee which may be payable in connection with that application under the **[**[F2]Medicines (Products for Human Use) (Fees) Regulations 2010**]**.

[[F3](2A) No fee need accompany a request where arrangements have been made with the licensing authority for payment of the fee referred to in paragraph (2)(b)(ii) other than at the time of request.**]**

(3) The request and any accompanying material shall be supplied in the English language.

Textual Amendments

F1 Words in reg. 17(2) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **11(a)**

F2 Words in reg. 17(2)(b)(ii) substituted (1.4.2010) by The Medicines (Products for Human Use) (Fees) Regulations 2010 (S.I. 2010/551), regs. 1, **51(2)**

F3 Reg. 17(2A) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **11(b)**