STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Reference to the appropriate committee or the Medicines Commission

26.—(1) If—

(a) a sponsor has been notified by the licensing authority that—

(i) there are grounds for not accepting a request for authorisation, or

(ii) in accordance with regulation 18(2) or (6), 19(8) or 20(5), the trial is authorised subject to specified conditions;

(b) the licensing authority has amended a clinical trial authorisation under regulation 23; or

(c) the sponsor who has been notified by the licensing authority in accordance with regulation 24(4) or 25(3) that—

(i) the authority does not accept a proposed, modified or adapted amendment to the clinical trial authorisation, or

(ii) the authority accepts such an amendment subject to conditions,

the sponsor may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice in writing to the licensing authority of his wish to make written or oral representations to the appropriate committee or, if for the time being there is no such committee, the Medicines Commission(**1**).

(2) Schedule 5 shall have effect to regulate the procedure for reference to the appropriate committee, or as the case may be, the Medicines Commission following receipt of a notice in accordance with paragraph (1).

(**1**) *See* section 2 of the Act.