SCHEDULE 5

Regulations 26(2) and 31(8)

PROCEDURAL PROVISIONS RELATING TO THE REFUSAL OR AMENDMENT OF, OR IMPOSITION OF CONDITIONS RELATING TO, CLINICAL TRIAL AUTHORISATION AND THE SUSPENSION OR TERMINATION OF CLINICAL TRIALS

1.—(1) Where the licensing authority are notified of the sponsor's wish to make representations in accordance with regulation 26(1) or 31(7) the authority shall afford an opportunity for the sponsor to make written or oral representations to the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

(2) After considering the representations, the appropriate committee or the Medicines Commission shall report their findings and advice, and the reasons for their advice, to the licensing authority.

(3) In the case of a decision not to accept a request for authorisation or an amendment to the clinical trial authorisation, the licensing authority shall, after considering the report of the appropriate committee or the Commission—

(a) confirm that they have grounds for not accepting the request or amendment; or

(b) accept the request for authorisation or amendment to the clinical trial authorisation, subject to such conditions as the licensing authority may consider appropriate.

(4) In the case of a decision to impose a condition following a request for authorisation or notice of amendment, the licensing authority shall, after considering the report of the appropriate committee or the Commission—

(a) confirm their decision; or

(b) remove or alter the condition in question.

(5) In the case of a notice to suspend or terminate a trial, the licensing authority shall, after considering the report of the appropriate committee or the Commission, confirm or revoke the notice.

(6) The licensing authority shall give notice to the sponsor of—

(a) the findings and advice of the appropriate committee or the Medicines Commission and the reasons for it; and

(b) their decision in accordance with sub-paragraphs (3), (4) or (5).

2.—(1) If a person to whom a notice is given under paragraph 1(6) is dissatisfied and he has not made representations to the Medicines Commission under paragraph 1(1), he may give notice in writing to the licensing authority within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given of his wish to make written or oral representations to the Medicines Commission.

(2) On receipt of a notice under sub-paragraph (1) the licensing authority shall afford an opportunity for the sponsor to be heard by the Medicines Commission or, as the case may be, for his written representations to be considered by them.

(3) After considering the representations the Medicines Commission shall report their findings and advice, and the reasons for their advice, to the licensing authority.

(4) After considering the report of the Medicines Commission, the licensing authority shall—

(a) confirm or alter their decision under paragraph 1(3), (4) or (5); and

(b) give notice to the person of—

(i) the findings and advice of the Medicines Commission and the reasons for it, and

(ii) the licensing authority's confirmation or alteration of their decision under paragraph 1(3) to (5).

3.—(1) If a decision notified in accordance with paragraphs 1(6) or 2(4) is a decision to which this paragraph applies, the sponsor may within the time allowed after the notification was given, give notice of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to the decision referred to in the notification.

(2) Where the sponsor gives notice under sub-paragraph (1) of his wish to appear before and be heard by a person appointed for the purpose by the licensing authority, the licensing authority shall make that appointment and—

(a) the person so appointed shall not, except with the consent of the applicant or holder, be an officer or servant of any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of the Act;

(b) if the applicant or holder so requests, the hearing shall be in public; and

(c) if the applicant or holder so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(3) The licensing authority shall take into account the report of the person appointed and decide whether to confirm or alter their decision.

(4) The decisions to which this paragraph applies are decisions of the licensing authority—

(a) to confirm—

(i) that they have grounds for not accepting a request for authorisation or an amendment to the clinical trial authorisation,

(ii) their decision to impose a condition, or

(iii) the notice to suspend or terminate the trial,

against the advice of the Medicines Commission under paragraph 1(2);

(b) to impose conditions in accordance with paragraph 1(3)(b) or alter a condition in accordance with paragraph 1(4)(b), in a way which differs from the advice given by the Medicines Commission under paragraph 1(2); or

(c) to confirm a decision under paragraph 1(3), (4) or (5) against the advice of the Medicines Commission under paragraph 2(3);

(d) to alter a decision under paragraph 1(3), (4) or (5) in a way which differs from the advice of the Medicines Commission under paragraph 2(3).