

SCHEDULE 5

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

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).