SCHEDULE 3

Regulation 4

AMENDMENTS TO THE CLINICAL TRIALS REGULATIONS

1. In regulation 2 (interpretation), in paragraph (1), for the definition of "appropriate committee" substitute—

""appropriate committee", for the purposes of any provision of these Regulations under which a function falls to be performed, means—

(a) in a case where—

(i) a committee has been established under section 4 of the Act for purposes which consist of or include any of those specified in subsection (3) of that section, and

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission on Human Medicines established by section 2A of the Act;".

2. In regulation 19 (authorization procedure for clinical trials involving medicinal products for gene therapy etc), in paragraph (10), in sub-paragraph (a), for "Committee on Safety of Medicines" substitute "Commission on Human Medicines established by section 2A of the Act".

3. In regulation 26 (reference to appropriate committee or the Medicines Commission)—

(a) in paragraph (1)—

(i) in sub-paragraph (c)—

(aa) omit "who", and

(bb) for "24(4)", substitute "24(5)",

(ii) omit "or, if for the time being there is no such committee, the Medicines Commission".

(b) in paragraph (2), omit ", or as the case may be, the Medicines Commission".

4.—(1) Regulation 31 (suspension or termination of clinical trial) shall be amended as follows.

(2) In paragraph (7), omit "or, if for the time being there is no such committee, the Medicines Commission".

(3) In paragraph (8), omit "or, as the case may be, the Medicines Commission".

(4) In paragraph (9), omit "or the Medicines Commission".

5. For Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorizations and the suspension or termination of clinical trials), substitute the following Schedule—

"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 AUTHORISATIONS AND THE SUSPENSION OR TERMINATION OF CLINICAL TRIALS

Hearing before the appropriate committee

1.—(1) Where the licensing authority are notified of the wish of a sponsor or investigator to make representations in accordance with regulation 26(1) or 31(7), the authority shall

inform the appropriate committee and the committee shall give the sponsor or investigator an opportunity to make such representations in accordance with sub-paragraphs (2) to (5).

(2) Subject to sub-paragraph (3), the sponsor or investigator shall provide the appropriate committee with—

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (1), or within such shorter period as the licensing authority may specify in the notification referred to in sub-paragraph (1).

(3) If the sponsor or investigator so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (2), up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (1).

(4) The sponsor or investigator may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (2) and (3) has expired, except with the permission of the appropriate committee.

(5) If the sponsor or investigator gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (3), arrange for the sponsor or investigator to make such representations at a hearing before the committee.

(6) The appropriate committee shall—

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

Licensing authority decision

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

(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.

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

(a) confirm their decision; or

(b) remove or alter the condition in question.

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

(4) The licensing authority shall give notice to the sponsor or investigator of—

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

(b) their decision in accordance with sub-paragraph (1), (2) or (3).

Right to be heard by a person appointed

3.—(1) Subject to sub-paragraph (2), if a sponsor or investigator to whom notice is given under paragraph 2(4) is dissatisfied, he may, within 28 days or such longer period as the licensing authority may in any particular case allow, of the notice being given—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the decision referred to in the notice.

(2) Sub-paragraph (1)(a) shall not apply where—

(a) the sponsor or investigator had not made any representations in accordance with paragraph 1(2) to (5); and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

(3) If the sponsor or investigator to whom notice is given under paragraph 2(4) makes written representations in accordance with sub-paragraph (2)(b), the licensing authority shall take those representations into account before deciding whether to confirm or alter their decision.

Hearing before person appointed

4.—(1) If a sponsor or investigator gives notice under paragraph 3(1)(a) of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the sponsor or investigator to have an opportunity of appearing before the person appointed by the licensing authority.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the sponsor or investigator shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the sponsor or investigator so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the sponsor or investigator fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether to confirm or alter their decision.

(6) The sponsor or investigator may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the sponsor or investigator and the licensing authority may make representations.

(8) If the sponsor or investigator so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to confirm or alter their decision.

(10) The licensing authority shall then—

(a) notify the sponsor or investigator of their decision;

(b) if the sponsor or investigator so requests, provide him with a copy of the report of the person appointed.".

6. In Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations), for paragraphs 4 and 5 substitute the following paragraphs—

"**4.**—(1) Subject to sub-paragraph (2), the applicant or holder to whom notice is given under paragraph 2 may, within the time allowed after the notification was given—

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the decision referred to in the notice.

(2) If the applicant or holder to whom notice is given under paragraph 2 makes written representations in accordance with sub-paragraph (1)(b), the licensing authority shall take those representations into account before deciding whether to—

(a) grant the authorisation,

(b) revoke, vary or suspend the authorisation, or

(c) confirm or alter their decision,

as the case may be.

5.—(1) If the applicant or holder gives notice under paragraph 4(1)(a) of his wish to appear before or be heard by a person appointed by the licensing authority, the authority shall—

(a) make that appointment; and

(b) arrange for the applicant or holder who gave notice to have an opportunity of appearing before the person appointed by the licensing authority.

(2) The person appointed—

(a) shall not be, or at any time have been, a member of—

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of the Act or any of its committees, or

(iii) a committee established under section 4 of the Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of a Minister of the Crown.

(3) Subject to sub-paragraph (4), the applicant or holder shall provide the person appointed with—

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1).

(4) If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3), up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1).

(5) If the applicant or holder fails to comply with the time limit in sub-paragraph (3) or, where he has been granted an extended time limit under sub-paragraph (4), that time limit—

(a) he may not appear before or be heard by the person appointed; and

(b) the licensing authority shall decide whether to grant the authoriSation, revoke, vary or suspend the authorisation or confirm or alter their decision, as the case may be.

(6) The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations.

(8) If the applicant or holder so requests the hearing shall be in public.

(9) After the hearing—

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to grant the authorisation, revoke, vary or suspend the authorisation or confirm or alter their decision, as the case may be.

(10) The licensing authority shall then—

(a) notify the applicant or holder of their decision;

(b) if the applicant or holder so requests, provide him with a copy of the report of the person appointed.”.