[F1SCHEDULE 5

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

Textual Amendments

F1 Sch. 5 substituted (30.10.2005) by The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 5**

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) **[**F2the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

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

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and**]**

(b) shall not be an officer or servant of a Minister of the Crown **[**F3, the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister**]**.

(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.**]**

Textual Amendments

F2 Sch. 5 para. 4(2)(a)(i)-(vii) substituted for Sch. 5 para. 4(2)(a)(i)-(iii) (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 61(a)** (with Sch. 32)

F3 Words in Sch. 5 para. 4(2)(b) inserted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 61(b)** (with Sch. 32)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Paragraph 4.