SCHEDULE 4 U.K.

Regulation 16(6)

APPEAL AGAINST UNFAVOURABLE ETHICS COMMITTEE OPINION

1.—(1) Subject to the following sub-paragraphs, where the United Kingdom Ethics Committee Authority ("the Authority") receive a notice pursuant to regulation 16(3) **[**[F1], (4)(b)**]** or (7) that a chief investigator wishes to appeal against an ethics committee opinion which is not favourable, the Authority shall, subject to sub-paragraph (2)—

(a) direct that the application for that opinion may be considered by another ethics committee specified in the direction; or

(b) appoint a panel in accordance with paragraph 3 ("an appeal panel") and refer the opinion to that panel.

(2) Subject to sub-paragraph (4), the Authority may refuse to give a direction or appoint a panel pursuant to sub-paragraph (1) where it considers that the grounds for appealing against the opinion are unfounded.

(3) Where the Authority refuse to give a direction or appoint a panel pursuant to sub-paragraph (1), the Authority shall send a notice to the chief investigator setting out their reasons for refusal.

(4) Where the opinion was given by the Gene Therapy Advisory Committee, the Authority must appoint a panel in accordance with paragraph 3 and refer the opinion to that panel.

Textual Amendments

F1 Word in Sch. 4 para. 1(1) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **30(a)**

2. Where a direction is given in accordance with paragraph 1(1)(a)—

(a) the ethics committee which gave the unfavourable opinion shall—

(i) send the application for that opinion, and

(ii) any additional information provided by the chief investigator,

to the ethics committee specified in the direction; and

(b) that committee shall consider the application in accordance with regulation 15.

3.—(1) An appeal panel appointed pursuant to paragraph 1(1)(b) shall consist of a chairman and at least 6 other members.

(2) One of the members shall be a person who is not—

(a) a health care professional,

(b) a person having professional qualifications or experience relating to the conduct of, or use of statistics in, clinical trials, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment, or

(c) a person who, although not a health care professional, has been a registered medical practitioner or a person registered in the dentists register under the Dentists Act 1984.

4.—(1) An appeal panel shall consider an ethics committee opinion referred to it in accordance with the following sub-paragraphs.

(2) The appeal panel shall consider—

(a) the opinion;

(b) the application for that opinion;

(c) the particulars and documents accompanying that application;

(d) the matters specified in regulation 15 **[**F2(5)**]**;

(e) any representations set out in the notice to the Authority; and

(f) in a case where the opinion has been confirmed by the Gene Therapy Advisory Committee F3... pursuant to regulation 16 **[**F4(6)**]**, the reasons given by the Committee for that confirmation.

(3) The panel may, if the chief investigator so requests, hold a hearing to consider the opinion, at which the chief investigator may make oral representations.

(4) The panel shall within 30 days of the opinion being referred to the panel, or such extended period as the Authority may in any particular case allow, either confirm the opinion or give a favourable opinion.

Textual Amendments

F2 Word in Sch. 4 para. 4(2)(d) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **30(b)(i)**

F3 Words in Sch. 4 para. 4(2)(f) omitted (29.8.2006) by virtue of The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **30(b)(ii)(aa)**

F4 Word in Sch. 4 para. 4(2)(f) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **30(b)(ii)(bb)**

5. If an appeal panel gives a favourable opinion, the condition specified in regulation **[**F512**]**(3)(a) shall be deemed to have been satisfied.

Textual Amendments

F5 Word in Sch. 4 para. 5 substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **30(c)**

6. The Authority may pay to members of an appeal panel such travelling and other allowances as the Authority may determine.

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