STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Amendments by the sponsor

24.—(1) A sponsor may make an amendment to a clinical trial authorisation, other than a substantial amendment, at any time.

(2) A sponsor shall—

(a) keep records of the amendments made in accordance with paragraph (1); and

(b) send those records, or copies of such records, to the licensing authority, where the authority send him a notice in writing requiring him to provide those records, or copies of such records.

(3) If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to—

(a) the terms of the request for authorisation of the clinical trial; or

(b) the particulars or documents that accompanied that request,

he shall send a valid notice of amendment to the licensing authority, whether or not he is also required to send a notice in accordance with paragraph (4).

(4) If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to—

(a) the terms of the application for an ethics committee opinion in relation to the clinical trial; or

(b) the particulars or documents that accompanied that application,

he shall send a valid notice of amendment to the relevant ethics committee, whether or not he is also required to send a notice in accordance with paragraph (3).

(5) The licensing authority may, within the period of 35 days from the date of receipt of a valid notice of amendment, give written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the proposed amendment; or

(b) stating that the licensing authority accepts the application for amendment, subject to any conditions which may be specified in the notice.

(6) A relevant ethics committee shall, within the period of 35 days from the date of receipt of a valid notice of amendment, give an opinion to the sponsor.

(7) Subject to paragraph (8), if the sponsor has sent a notice in accordance with paragraph (3), he may make the amendment only if—

(a) the licensing authority have given him a notice in accordance with paragraph (5)(b); or

(b) no notice has been given by the licensing authority in accordance with paragraph (5).

(8) If the sponsor has been given a notice in accordance with paragraph (5)(b), he may make the amendment subject to the conditions, if any, specified in the notice.

(9) If the sponsor has sent a notice in accordance with paragraph (4), he may make the amendment only if the relevant ethics committee has given a favourable opinion.

(10) In this regulation—

"valid notice of amendment" means a notice that is—

(a) in writing; and

(b) accompanied by—

(i) the particulars specified in Part 3 of Schedule 3, and

(ii) any fee which may be payable in connection with that notice under the Medicines (Products for Human Use—Fees) Regulations 1995(**1**).

(**1**) S.I. 1995/1116.