STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Authorisation procedure for clinical trials involving general medicinal products

18.—(1) This regulation applies to clinical trials involving medicinal products other than those to which regulations 19 and 20 apply.

(2) The licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial to which this regulation applies, give written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the request;

(b) stating that the licensing authority accepts the request for authorisation; or

(c) stating that the licensing authority accepts the request for authorisation, subject to the conditions specified in the notice.

(3) Subject to paragraph (4), if—

(a) a notice is given in accordance with paragraph (2)(b); or

(b) no notice is given in accordance with paragraph (2),

the clinical trial is to be treated as authorised.

(4) If a notice is given in accordance with paragraph (2)(c), the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied.

(5) If the sponsor is given a notice in accordance with paragraph (2)(a) or (c), he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration.

(6) The licensing authority shall consider a valid amended request and may, within the period of 60 days from the date on which the original request was received give a written notice to the sponsor—

(a) setting out the licensing authority's grounds for not accepting the amended request;

(b) stating that the licensing authority accepts the amended request; or

(c) stating that the licensing authority accepts the amended request, subject to the conditions specified in the notice.

(7) Subject to paragraph (8), if a valid amended request has been received and—

(a) a notice is given in accordance with paragraph (6)(b); or

(b) no notice is given in accordance with paragraph (6),

the clinical trial is to be treated as authorised.

(8) If a valid amended request has been received and a notice is given in accordance with paragraph (6)(c), the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied.

(9) If—

(a) the licensing authority gives written notice to the sponsor of grounds for non-acceptance in accordance with paragraph (2)(a) and the sponsor does not submit an amended request in accordance with paragraph (5), or

(b) the sponsor has submitted an amended request in accordance with paragraph (5), but the licensing authority gives written notice to the sponsor of grounds for non-acceptance in accordance with paragraph (6)(a),

the request is to be treated as rejected and the authority shall not consider any further amendments to the request.