STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 4

GOOD CLINICAL PRACTICE AND THE CONDUCT OF CLINICAL TRIALS

Suspension or termination of clinical trial

31.—(1) If, in relation to a clinical trial—

(a) the licensing authority have objective grounds for considering that—

(i) any condition, restriction or limitation which applies to the conduct of the trial and is set out in the request for authorisation or the particulars or documents accompanying that request, or

(ii) any condition imposed by the licensing authority under regulation 18(2) or (6), 19(8), 20(5), 24(4) or Schedule 5,

is no longer satisfied (either generally or at a particular trial site); or

(b) the licensing authority have information raising doubts about the safety or scientific validity of the trial, or the conduct of the trial at a particular trial site,

the licensing authority may, by a notice served in accordance with paragraph (2), require that the trial, or the conduct of the trial at a particular trial site, be suspended or terminated.

(2) A notice in accordance with paragraph (1) shall be served—

(a) in a case where the suspension or termination applies to the trial generally, on—

(i) the sponsor, or

(ii) the investigator at each trial site;

(b) in a case where the suspension or termination applies to the conduct of a trial at a particular trial site, on—

(i) the sponsor, or

(ii) the investigator at that trial site.

(3) The notice shall specify—

(a) whether the notice applies to the trial generally or to one or more of the trial sites;

(b) whether the notice requires suspension or termination of the trial;

(c) if the notice requires suspension of the trial—

(i) whether the suspension applies until further notice from the licensing authority or for such period as may be specified in the notice, and

(ii) any conditions which are to be satisfied before the trial or, as the case may be, the conduct of the trial at a particular site, may be recommenced; and

(d) whether suspension or termination is to take effect immediately on receipt of the notice or on such date as may be specified in the notice.

(4) If the licensing authority issues a notice under paragraph (1), they shall forthwith inform—

(a) where the notice has not been served on the sponsor, the sponsor;

(b) competent authorities of each EEA State, other than the United Kingdom;

(c) the relevant ethics committee;

(d) the European Medicines Agency; and

(e) the European Commission.

(5) Subject to paragraph (6), at least one week before issuing a notice under paragraph (1) the licensing authority shall, by a notice in writing to the sponsor or the investigator—

(a) inform him that the authority is minded to issue a notice suspending or terminating the trial, or the conduct of a trial at a particular site, and of the reasons why they are so minded; and

(b) advise him that they may, within one week of the date of the notice, furnish the authority with written representations as to whether the trial, or the conduct of the trial at a particular site, should be so suspended or terminated.

(6) Paragraph (5) shall not apply where it appears to the licensing authority that there is an imminent risk to the health or safety of any of the subjects of the clinical trial.

(7) A person on whom a notice has been served in accordance with paragraphs (1) and (2) may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice of his wish to make written or oral representations to the appropriate committee or, if for the time being there is no such committee, the Medicines Commission.

(8) Schedule 5 shall have effect to regulate the procedure for reference to the appropriate committee or, as the case may be, the Medicines Commission(**1**) following receipt of a notice in accordance with paragraph (7).

(9) Where the notice of suspension or termination is referred to an appropriate committee or the Medicines Commission it shall remain in force unless revoked in accordance with Schedule 5.

(**1**) *See* section 2 of the Act.