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

Good clinical practice and protection of clinical trial subjects

28.—(1) No person shall—

(a) conduct a clinical trial; or

(b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),

otherwise than in accordance with the conditions and principles of good clinical practice.

(2) Subject to paragraph (5), the sponsor of a clinical trial shall put and keep in place arrangements for the purpose of ensuring that with regard to that trial the conditions and principles of good clinical practice are satisfied or adhered to.

(3) Subject to paragraphs (4) and (5), the sponsor of a clinical trial shall ensure that—

(a) the investigational medicinal products used in the trial, and

(b) any devices used for the administration of such products,

are made available to the subjects of the trial free of charge.

(4) The restriction in paragraph (3) shall not apply in relation to any charge payable by a subject under regulations made under—

(a) the National Health Service Act 1977(**1**);

(b) the National Health Service (Scotland) Act 1978(**2**); or

(c) the Health and Personal Social Services (Northern Ireland) Order 1972(**3**),

in respect of any medicinal products or devices provided in pursuance of those Acts or that Order.

(5) If—

(a) a clinical trial is conducted at more than one trial site; and

(b) the request for authorisation to conduct that trial specifies that in relation to one or more trial sites the duties of the sponsor under paragraphs (2) and (3) are to be performed by a person other than the sponsor,

those duties shall, in relation to that site or those sites, be performed by the person so specified.

(**1**) 1977 c. 49.
(**2**) 1978 c. 29.
(**3**) S.I. 1972/1265 (N.I. 14).

Conduct of trial in accordance with clinical trial authorisation etc.

29. Subject to regulation 30, no person shall conduct a clinical trial otherwise than in accordance with—

(a) the protocol relating to that trial, as may be amended from time to time in accordance with regulations 22 to 25;

(b) the terms of—

(i) the request for authorisation to conduct that trial,

(ii) the application for an ethics committee opinion in relation to that trial, and

(iii) any particulars or documents, other than the protocol, accompanying that request or that application,

as may be amended from time to time in accordance with regulations 22 to 25; and

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

Urgent safety measures

30.—(1) The sponsor and investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety.

(2) If measures are taken pursuant to paragraph (1), the sponsor shall immediately, and in any event no later than 3 days from the date the measures are taken, give written notice to the licensing authority and the relevant ethics committee of the measures taken and the circumstances giving rise to those measures.

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(**4**) 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.

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