STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 1

INTRODUCTORY PROVISIONS

Sponsor of a clinical trial

3.—(1) In these Regulations, subject to the following paragraphs, "sponsor" means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

(2) If two or more persons take responsibility for the matters specified in paragraph (1) in relation to a clinical trial, those persons may—

(a) take joint responsibility for carrying out the functions of the sponsor of that trial under these Regulations; or

(b) allocate responsibility for carrying out the functions of the sponsor of that trial in accordance with paragraphs (4) to (10).

(3) If two or more persons take joint responsibility in accordance with paragraph (2)(a)—

(a) any reference to the sponsor in these Regulations shall, in relation to that trial, be construed as a reference to those persons; and

(b) paragraphs (4) to (10) shall not apply.

(4) One of the persons referred to in paragraph (2) shall be responsible for carrying out the functions of a sponsor under Part 3 (authorisation for clinical trials and ethics committee opinion) and shall make the request for authorisation to conduct the trial in accordance with regulation 17.

(5) The request for authorisation referred to in regulation 17 shall specify—

(a) who, in accordance with paragraph (4), is responsible for carrying out the functions of the sponsor under Part 3;

(b) who is to be responsible for carrying out the functions of the sponsor under Part 4 (good clinical practice and the conduct of clinical trials); and

(c) who is to be responsible for carrying out the functions of the sponsor under Part 5 (pharmacovigilance).

(6) After the clinical trial has been authorised by the licensing authority in accordance with regulation 18, 19 or 20, a different person may be specified as responsible for carrying out the functions of the sponsor under Part 3, 4 or 5 by making a substantial amendment to the terms of a clinical trial authorisation in accordance with regulations 24 to 26.

(7) Where a person is responsible for carrying out the functions of the sponsor under Part 3 by virtue of paragraph (5), or is specified in accordance with paragraph (6) as responsible for those functions, any reference to the sponsor in—

(a) that Part, except regulation 15,

(b) Parts 2 to 4 of Schedule 3,

(c) Schedule 5, in so far as it relates to decisions of the licensing authority under Part 3, and

(d) Schedule 12,

shall, in relation to the trial, be construed as a reference to that person.

(8) Where a person is specified in accordance with paragraph (5) or (6) as responsible for carrying out the functions of the sponsor under Part 4, any reference to the sponsor in—

(a) that Part, except regulation 28(1), or

(b) Schedule 5, in so far as it relates to notices under regulation 31(1),

shall, in relation to the trial, be construed as a reference to that person.

(9) Where a person is specified in accordance with paragraph (5) or (6) as responsible for carrying out the functions of the sponsor under Part 5, any reference to the sponsor in that Part shall, in relation to the trial, be construed as a reference to that person.

(10) Any reference to the sponsor in—

(a) regulations 15 and 28(1),

(b) Parts 2 and 6 to 9, and

(c) Schedules 1 and 7, and Part 1 of Schedule 3,

shall, in relation to the trial, include a reference to a person specified in accordance with paragraph (5) or (6).

(11) A person who is a sponsor of a clinical trial in accordance with this regulation must—

(a) be established in the European Community, or

(b) have a legal representative who is so established.