STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Requirement for authorisation and ethics committee opinion

12.—(1) No person shall—

(a) start a clinical trial or cause a clinical trial to be started; or

(b) conduct a clinical trial,

unless the conditions specified in paragraph (3) are satisfied.

(2) No person shall—

(a) recruit an individual to be a subject in a trial;

(b) issue an advertisement for the purpose of recruiting individuals to be subjects in a trial,

unless the condition specified in paragraph (3)(a) has been satisfied.

(3) The conditions referred to in paragraphs (1) and (2) are—

(a) an ethics committee or an appeal panel appointed under Schedule 4 has given a favourable opinion in relation to the clinical trial; and

(b) the clinical trial has been authorised by the licensing authority.

(4) For the purposes of these Regulations, a clinical trial has been authorised by the licensing authority if—

(a) in the case of a trial to which regulation 18 relates—

(i) the trial is to be treated as authorised by virtue of regulation 18, or

(ii) the authority has accepted the request for authorisation in accordance with the procedure specified in Schedule 5; or

(b) in the case of a clinical trial to which regulation 19 or 20 applies—

(i) the authority has given a notice of authorisation in accordance with those regulations, or

(ii) the authority has accepted the request for authorisation in accordance with the procedure specified in Schedule 5.