STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Amendments by the licensing authority

23.—(1) Subject to paragraphs **[**F1(2) and (3)**]**, the licensing authority may make amendments to a clinical trial authorisation if it appears to the authority to be necessary to ensure—

(a) the safety or scientific validity of the clinical trial; or

(b) that the conditions and principles of good clinical practice are satisfied or adhered to in relation to the clinical trial.

(2) Where the licensing authority propose to make an amendment in accordance with paragraph (1), the authority shall, at least 14 days before the date on which it is proposed the amendment should take effect, serve a notice on the sponsor stating their proposal and the reasons for it.

(3) If, within 14 days of the date a notice is served in accordance with paragraph (2), the sponsor makes representations in writing to the licensing authority, the authority—

(a) shall take those representations into account before deciding whether to make the amendment; and

(b) may delay the date the proposed amendment is to take effect, in order to allow time for them to consider those representations.

Textual Amendments

F1 Words in reg. 23(1) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **12**

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 23.