STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Interpretation of Part 3

11. In this Part—

"amendment to the clinical trial authorisation" means an amendment to—

(a) the terms of the request for authorisation to conduct that trial or the application for an ethics committee opinion in relation to that trial,

(b) the protocol for that trial, or

(c) the other particulars or documents accompanying that request for authorisation or application for ethics committee approval;

"substantial amendment to the clinical trial authorisation" means an amendment to the clinical trial authorisation which is likely to affect to a significant degree—

(a) the safety or physical or mental integrity of the subjects of the trial,

(b) the scientific value of the trial,

(c) the conduct or management of the trial, or

(d) the quality or safety of any investigational medicinal product used in the trial;

"valid application" means an application for an ethics committee opinion which complies with the provisions of regulation 14; and

"valid request for authorisation" means a request to the licensing authority for authorisation to conduct a clinical trial which complies with the provisions of regulation 17, and "valid amended request" shall be construed accordingly.