
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 8

ENFORCEMENT AND RELATED PROVISIONS

False or misleading information

50.—(1) Any person who in the course of—

- (a) making an application for an ethics committee opinion;
- (b) making a request for authorisation to conduct a clinical trial; or
- (c) making an application for the grant or variation of a manufacturing authorisation,

provides to the licensing authority or an ethics committee any relevant information which is false or misleading in a material particular shall be guilty of an offence.

(2) Any person who—

- (a) is conducting a clinical trial authorised in accordance with these Regulations;
- (b) is a sponsor of such a clinical trial;
- (c) while acting under arrangements made with a sponsor of such a clinical trial, performs the functions of that sponsor; or
- (d) holds a manufacturing authorisation,

and who, for the purposes of these Regulations, provides to the licensing authority or an ethics committee any relevant information which is false or misleading in a material particular shall be guilty of an offence.

(3) Any person who, for the purpose of being engaged as a qualified person in accordance with regulation 43, provides to the licensing authority or to the holder of a manufacturing authorisation any information which is false or misleading in a material particular shall be guilty of an offence.

(4) In this regulation, “relevant information” means any information which is relevant to an evaluation of—

- (a) the safety, quality or efficacy of an investigational medicinal product;
- (b) the safety or scientific validity of a clinical trial; or
- (c) whether, with regard to a clinical trial, the conditions and principles of good clinical practice are being satisfied or adhered to.