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.