STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 8

ENFORCEMENT AND RELATED PROVISIONS

Application of enforcement provisions of the Act

47.—(1) Sections 107 to 116, 118, 119, 121 to 125, 127, 129, 131 and 132(1) of, and Schedule 3 to, the Act shall apply for the purposes of these Regulations, but with the modifications specified in Schedule 9.

(2) In those provisions as applying by virtue of paragraph (1), a reference to any part of those provisions or a part of any of them is a reference to the provision or part as so applying.

Infringement notices

48.—(1) If an enforcement authority have objective grounds for considering that any person has contravened any provision to which this regulation applies, they may serve upon that person a notice in writing (in these Regulations referred to as an "infringement notice")—

(a) informing him of the authority's grounds for considering that the person has contravened one or more of those provisions;

(b) specifying the relevant provision of these Regulations;

(c) specifying the measures which the person must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;

(d) requiring the person to take those measures, within such period as may be specified in the notice;

(e) warning the person that unless the requirements of sub-paragraph (d) are met, further action may be taken in respect of the contravention.

(2) An infringement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance.

(3) If an enforcement authority serves an infringement notice in accordance with paragraph (1), they shall forthwith inform—

(a) the competent authorities of each EEA State, other than the United Kingdom;

(b) the relevant ethics committee; and

(c) the European Commission.

(4) This regulation applies to regulations 22(b), 27, 28(1) to (3), 29, 30(2) and 32 to 35.

(5) In this regulation, "enforcement authority" means any Minister or body on whom a duty or power to enforce any provisions of these Regulations is imposed or conferred by or under sections 108 to 110 of the Act as applied by regulation 47.

Offences

49.—(1) Any person who contravenes any of the following provisions—

(a) regulation 12(1) and (2);

(b) regulation 13(1);

(c) regulation 27;

(d) regulation 28(1) to (3);

(e) regulation 29;

(f) regulation 30(2);

(g) regulation 32(1), (3), and (5) to (9)

(h) regulation 33(1) to (5)

(i) regulation 34

(j) regulation 35(1);

(k) regulation 36(1);

(l) regulation 42; and

(m) regulation 43(1) and (6),

shall be guilty of an offence.

(2) Any person who has in his possession a medicinal product for the purpose of selling or supplying it in contravention of regulation 13(1) shall be guilty of an offence.

(3) Any person who fails to comply with a notice of suspension or termination served on him under regulation 31, unless that notice has been withdrawn or revoked by the licensing authority, shall be guilty of an offence.

(4) Where an investigational medicinal product is manufactured, assembled or imported in contravention of regulation 36(1), any person who sells or supplies the product for the purposes of a clinical trial knowing or having reasonable cause to suspect that it was so manufactured, assembled or imported shall be guilty of offence.

(5) Where an investigational medicinal product is imported in contravention of regulation 36(1), any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under these Regulations, the Act or any other enactment, is in possession of the product knowing or having reasonable cause to suspect that it was so imported shall be guilty of offence.

(6) Any sponsor who sells or supplies, or procures the sale or supply, of an investigational medicinal product—

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the product to such a subject,

the labelling of which does not comply with regulation 46, shall be guilty of an offence.

(7) Any person who sells or supplies an investigational medicinal product—

(a) to a subject for the purposes of a clinical trial; or

(b) to a person for the purpose of administering the product to such a subject,

the labelling of which does not comply with regulation 46, knowing, or having reasonable cause to believe, that the labelling does not so comply, shall be guilty of an offence.

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.

Defence of due diligence

51.—(1) A person does not commit an offence under these Regulations if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Penalties

52. A person guilty of an offence under these Regulations shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both;

(b) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.